Exhibit B

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	: SUPERIOR COURT OF
	: NEW JERSEY
IN RE:	: LAW DIVISION -
PELVIC MESH/GYNECARE	: ATLANTIC COUNTY
LITIGATION	:
	: MASTER CASE 6341-10
(GENERAL, GROSS, WICKER)	:
	: CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

- - -

Monday, November 5, 2012

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Transcript of the deposition of ANNE M. WEBER, M.D., M.S., called for examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure by and before Kimberly A. Overwise, a Certified Realtime Reporter, Registered Professional Reporter, Certified Court Reporter, and Notary Public, at Mazie, Slater, Katz & Freeman, 103 Eisenhower Parkway, 2nd Floor, Roseland, New Jersey, on the above date, beginning at 9:41 a.m.

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No Confidential Designations Submitted for Volume I.

CONFIDENTIAL DESIGNATION INDEX

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...ANNE M. WEBER, M.D., M.S., after having been duly sworn, was examined and testified as follows:

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EXAMINATION

BY MS. JONES:

Q Doctor, would you state your name and address for the record, please?

A My name is Anne Margaret Weber. My address is 5626 Sharon Drive in Glen Arm -- two words with a capital A -- Maryland 21058.

Q And is that your home address?

A Yes.

Q Do you have a separate business address at this point?

A No.

Q And are you currently employed, Doctor?

A I'm employed in consulting.

Q Do you have a separate consulting company?

A No. I'm not personally incorporated.

Q When you say that you are engaged in consulting, what kind of consulting are you engaged in?

A Consulting on this case.

Q And that would be in litigation involving

pelvic mesh; correct?

A That's this case, yes.

Q And can you tell me when you were first retained in this case?

A I began working in February of 2010.

Q By whom were you first contacted?

A I believe it was by Beth Baldinger of Adam's firm.

Q And approximately when was that?

A I believe it was in the fall of 2009.

Q And you said that you did not start working on this case until the spring of 2010?

A February, yes.

Q What happened in that interim between being contacted and actually starting working on this case?

A At some time later Adam contacted me and we talked in more detail about exactly what the work would involve and to make the specific arrangements to go ahead.

Q And what was your understanding about the work involved?

A To review documents from the company and draw opinions about the product.

Q And when you say "about the product," was

there a specific product that you were asked to evaluate?
A The Prolift® product and procedure.
Q And was it just the original Prolift® or was it Prolift+M® as well?
A Just the original Prolift®.
Q And has that remained your charge throughout until today?
A Yes.
Q Have you previously given a deposition?
A Yes.
Q On how many occasions?
A Twice.
Q Can you tell me in what context? Was that as a consultant, an expert witness?
A One of the cases I served as an expert witness for the defense and in the other case I was one of the litigants.
Q Let's talk about when you served as an expert witness for the defense. What type of case was that?
A Medical malpractice.
Q Do you remember the style of the case or the names of the parties involved?
A The doctor was Dr. Neil Jackson. I don't

remember the plaintiff.
Q Where was the case pending?
A The doctor was from Providence. The case was in Newport, Rhode Island.
Q Did you actually testify at trial or just by deposition?
A Yes, I testified at trial.
Q What were the alleged injuries in that case?
A The woman had voiding dysfunction after reconstructive surgery.
Q What type of reconstructive surgery?
A I don't remember.
Q I take it it would have been some type of pelvic floor repair surgery?
A Yes.
Q Did that case involve the use of mesh?
A I don't remember.
Q Who was the lawyer by whom you were retained?
A I don't remember.
Q And did you give only one deposition at that time?
A Yes.
Q Now, you said that you were also deposed

in a case in which you were a litigant. Can you tell me about that, please?
A Yes. A patient I had seen once while I was on faculty at the Cleveland Clinic brought a claim against the clinic.
Q And were you named as a party?
A Yes.
Q Presumably that was a medical malpractice claim?
A I believe so.
Q Did that case go to trial?
A It was dismissed.
Q Do you remember the name of the plaintiff?
A No.
Q About when did you give that deposition?
A I believe it was in around 2002.
Q It was after you had left the Cleveland Clinic then?
A Yes.
Q And what were the allegations in that case?
A This woman subsequently developed infertility and believed that she should have been offered egg retrieval as an option in her past, at which time it wasn't even feasible.

Q When you say she subsequently developed infertility, did she develop infertility as a result of a procedure or was the claim simply that she had not been given appropriate counseling and alternatives when being treated for infertility?
A I didn't treat her for infertility. I provided her with routine gynecologic care. And she subsequently developed infertility for unknown reasons. So her claim was that at the time I saw her for normal gynecologic care, I should have offered her options such as egg retrieval.
Q And your testimony in that case, was that case actually filed in Cleveland?
A I don't remember.
Q Your testimony in that case and the testimony in the Rhode Island case are the only two times that you have given depositions?
A Correct.
Q And you indicated that you are a consultant obviously as an expert witness in this litigation. Have you been a consultant in other litigation?
A No.
Q Other than your work here in this case, do you have any other source of income?

A Yes.
Q Tell me what that is.
A I receive disability for my medical condition. And we have investments --
MR. SLATER: She's not talking about your personal income.
BY MS. JONES:
Q I don't really want to go into your --
A Okay.
Q I don't want to go into your personal investment history and income and so forth. I didn't mean to pry in the sense of that. I'm just trying to figure out other --
MR. SLATER: Work that you do for third parties.
THE WITNESS: Yes.
BY MS. JONES:
Q -- work that you do for anyone else.
A Okay. I provide editorial reviews for the International Academy of Pelvic Surgery.
Q And are you compensated for that?
A Yes.
Q Are you on a salary --
A No.
Q -- with them?

And can you just tell me how you are compensated?
A It's $250 an hour.
Q And approximately how much time do you spend working with the International Academy of Pelvic Surgery?
A I would say eight hours a month.
Q I gather it would vary from time to time depending upon what you're doing?
A Well, I typically provide a monthly series of reviews of current medical literature.
Q I'm sorry. Would you say that again, please?
A I typically provide a review of the current medical literature.
Q And the current medical literature, is that limited to certain topics?
A To urogynecology.
Q And within the realm of urogynecology, is it limited to any more specialized area, stress urinary incontinence or pelvic organ prolapse or any other more specific area, or does it cover the whole broad spectrum of urogynecology?
A The broad spectrum of urogynecology.
Q And when you say you provide the review

article, are you required to conduct a search of the medical literature or are you instead furnished with literature and asked to prepare the review on previously identified literature?
A I search the literature myself and identify what seems relevant to me to comment on.
Q Let me see if I can go back. I got a little bit distracted here. Let me say, Doctor, you're standing. And before you came in, Mr. Slater advised that you intended to stand for portions of the day. And I take it that that is because of a physical condition that's more comfortable for you?
A Correct.
Q Let me just say although we're on a relatively tight schedule here, I want you to know if at any time you need to take a break or go walk around the block, if you'll just let me know, I'll be glad to accommodate it and do whatever we can. Okay?
A Thank you.
Q By the same token, if at any time you don't understand my questions or you need me to repeat something, if you'll stop me and ask me, I'll see what I can do to accommodate that.
A Yes.

Q You indicated earlier that you have disability income. Can you just tell me how long you have been disabled?
A I left my surgical practice in 2004.
Q And I don't want to pry, but can you just briefly describe for me was it your physical condition that led to you leaving your surgical practice?
A Yes.
Q Can you just give me an overview or just a generalization of what that disability is?
MR. SLATER: Let's go off the record for a second.
(Discussion off the record.)
BY MS. JONES:
Q What I've just asked, Doctor, is if you can just tell me what about your physical condition led to your disability from a surgical practice or affected your surgical practice.
A I have a pain condition that limits my ability to perform the kind of surgery I was trained to perform.
Q Does it limit your ability specifically to perform pelvic floor repair surgery?
A That is the surgery I was specifically

trained to perform.
Q I understand that. I guess what I'm asking is would it affect your ability to do other types of surgery?
A I would presume so.
Q You said that you left your surgical practice in 2004; is that right?
A Correct.
Q Was there a period of time before 2004 where you gradually began to reduce the number of surgeries that you performed as a result of this condition?
A No.
Q Did this condition have a precipitous onset?
THE WITNESS: Adam?
MR. SLATER: If you don't --
THE WITNESS: I just don't understand --
MR. SLATER: Let's go off the record. I object to the question.
(Discussion off the record.)
MR. SLATER: I have a hard time with that because obviously Dr. Weber doesn't want to talk in detail about her physical medical condition.

And, you know, she's trying to give you what she can, but she's obviously uncomfortable talking about this.
MS. JONES: All I really want to know is how it affected the surgical practice.
MR. SLATER: So why don't we just go with that question: What was it about your condition that impacted your ability to perform your surgical practice?
Are you okay with that? Because that I think is a relevant question.
THE WITNESS: It exacerbated my pain condition.
MR. SLATER: Can I help you for a second?
Are you talking about the physical requirements --
THE WITNESS: Yes.
MR. SLATER: -- on your body of performing surgery in the operating room --
THE WITNESS: Yes. It's very demanding.
MR. SLATER: -- that would exacerbate your condition?
THE WITNESS: Yes.

BY MS. JONES:
Q If we're talking about the different types of surgeries that you were performing in 2004, were you performing, for example, abdominal sacrocolpopexies?
A Yes.
Q And how long as a general matter would it take you to perform that surgery?
A It depends on the patient.
Q I understand that, but give me an idea. Would it be three or four hours?
A I would say two to four hours.
Q Were you also performing, for example, sling surgeries to repair urinary incontinence?
A Yes.
Q And how long would those procedures take?
A It would be very unusual for me to perform a sling in an isolated -- as an isolated procedure. This would be almost always in the context of a concomitant prolapse operation.
Q Other than the abdominal sacrocolpopexies, what types of other prolapse surgeries were you performing at that time?
A For apical prolapse, uterosacral ligament suspension. For anterior and posterior prolapse,

anterior and posterior colporrhaphy.
Q How long did it take you to perform an anterior colporrhaphy, for example?
A Again, it's very uncommon to have an isolated procedure like that. Very few women come in with one aspect of a pelvic floor disorder, at least to my practice.
Q Did all of the surgeries that you performed, whether it's the abdominal sacrocolpopexy or a TVT® sling procedure, equally affect your condition?
A My surgical practice consisted of a day of surgery. So when I was going to surgery, it was for the day.
Q How many days a week did you operate?
A One.
Q For what period of time would that have been true? This was when you were in Pittsburgh; correct?
A Correct. I expected you were referring to that, although that was also t rue for my clinical practice in Cleveland unless I needed extra time. Typically one day a week.
Q So from the time you were in Cleveland through the time you were in Pittsburgh, that was

your typical practice to have one day a week set aside for surgery?
A Correct.
Q Let me go back and ask you about the case where you testified. I think you told me the doctor's name was Neil Jackson?
A Yes.
Q When was that testimony?
A I don't remember exactly. I believe it was somewhere in the range of seven to ten years ago.
Q So sometime between 2002 and 2005 roughly?
A I think that's right.
Q Were you living in Pittsburgh at the time?
A Yes.
Q Were you still on staff in Pittsburgh?
A Yes.
Q Incidentally, when you ceased your surgical practice in 2004, did you remain on staff at the institution?
A Yes.
Q And am I correct that you did so until 2006?
A Yes.
Q Can you tell me what you did from 2004 to

2006 in that capacity?
A Yes. I remained the director of the fellowship. So I was responsible for working with the fellows. In the third year of the fellowship, they had office practice. So I continued my office practice through 2004 and 2005 working with the fellows in my office. And I continued to work with them to teach them and supervise them in performing their research. And I was also involved in performing my own research and I was also working for the NIH at that time.
Q When you said that in the third year they had an office practice, they would have basically what amounted to a private practice and they would see patients in the office?
A With one of the faculty, yes.
Q And did you continue to maintain an office practice through this time period?
A I did for 2004 and 2005.
Q And what did your office practice consist of?
A All patients with a urogynecology problem.
Q Was it limited at that point to urogynecology?
A Yes.

Q And when patients would come in to you in the context of an office practice, would you yourself actually examine the patients?
A Yes.
Q And then consult with the patients about the appropriate treatment for whatever condition they had?
A Yes; with the fellows.
Q That's kind of what my question is. Did you have a practice where you saw women individually without a fellow being present?
A No.
Q And so if a fellow was present, would the fellow under normal circumstances be the doctor that's examining the patient or would you both examine the patient?
A We both examined the patient.
Q And then in the event that the patient was a surgical candidate, would that patient then be referred elsewhere to surgery?
A She would be referred to one of my partners in the department with the fellow.
Q With the fellow that would --
A Follow her.
Q -- that was there with you?

A Yes, exactly.
Q Were you still engaged in surgery at the time you testified in Rhode Island?
A I don't remember.
Q Did you have to prepare a report in that case?
A I don't specifically remember.
Q Do you remember what your opinions were as they related to voiding dysfunction?
A I don't.
Q And I think you told me that you did not recollect whether or not mesh was in any way involved in that lawsuit?
A Correct, I did not remember.
Q I take it that you don't remember specifically rendering any opinions about the propriety of use of mesh or not then?
A No, I don't.
Q And certainly there can be issues of voiding dysfunction whether or not mesh is involved; correct?
A Yes.
Q That wasn't a very good question. Voiding dysfunction can be associated with a number of different pelvic floor surgeries; correct?

A Yes.
Q That would be one of the standard risks recognized by the medical community and known in the context of doing virtually any type of pelvic surgery; correct?
MR. SLATER: Objection to the form.
You can answer.
THE WITNESS: What do you mean by "standard"?
BY MS. JONES:
Q To be honest, I don't even remember how I used the word "standard" so let me rephrase the question.
Voiding dysfunction would be a recognized complication of most pelvic surgeries; correct?
MR. SLATER: Objection to the form.
You can answer.
THE WITNESS: There are gradations of voiding dysfunction that are very important to differentiate between the different types of surgery.
BY MS. JONES:
Q Can you explain that to me?
A By "gradations" I mean a spectrum ranging from mild to severe.

Q And that spectrum ranging from mild to severe may be associated with a variety of pelvic surgeries; correct?
A Yes.
Q And that is true whether or not those surgeries involve the use of mesh?
A I don't agree with that.
Q You don't agree that voiding dysfunction is a complication of surgeries that do not use mesh?
MR. SLATER: Objection to the form.
You can answer.
THE WITNESS: That wasn't what I understood you to ask me.
BY MS. JONES:
Q Well, that's my question.
A Could you repeat the question?
Q Sure. Is voiding dysfunction a recognized complication of pelvic surgeries that do not use mesh?
MR. SLATER: Objection to the form.
You can answer.
THE WITNESS: Yes.
BY MS. JONES:
Q You said that you last performed surgery in 2004; am I right?

A Yes.
Q Was that early 2004 or late 2004?
A I believe it was in the fall.
Q When was the last time that you were actually engaged in the practice of medicine?
A At the end of 2005.
Q And so in that interim between the fall of 2004 and the end of 2005, that would have been the time period in which you were seeing patients in an office setting with a fellow?
A Correct.
Q Do I understand correctly that you have not actually examined a patient since the end of 2005?
A Correct.
Q Have you provided any type of consultation to a patient since the end of 2005?
A No.
Q And that would include not written any prescriptions or advising or consulting about surgery or a medical condition?
A Correct.
Q I take it that you are not currently on staff at any hospital?
A Correct.

Q And have not been since 2005?
A I remained at Magee-Womens Hospital at the University of Pittsburgh until May 2006.
Q So during that six-month period from the end of 2005 until mid-2006, you would have remained on staff there?
A Correct.
Q But that would have been the only place that you had privileges at that point in time?
A Correct.
Q And since that point in time you have not had privileges elsewhere?
A Correct.
Q And I take it that obviously at some time you moved from Pittsburgh back to Maryland?
A Correct.
Q When was that?
A That was in June of this year.
Q June of 2012?
A Yes.
Q Did you remain in Pittsburgh in that interim?
A Yes.
Q What prompted your move to Maryland this year?

A My husband has a new job.
Q Your husband's not a medical doctor, is he?
A No.
Q You told us, Doctor, that you were first contacted in the fall of 2009 about this litigation?
A I believe that's correct.
Q And that you thought you actually began working on the case in February 2010?
A Yes.
Q When you say that you began working on the case in February of 2010, what does that mean? What did you begin doing?
A I began to review the Ethicon documents.
Q And those were all documents that would have been sent to you by plaintiffs' counsel?
A Yes.
Q Prior to beginning review of those documents, had you ever reviewed the internal documents of any device manufacturer?
A No.
Q Or any drug manufacturer?
A No.
Q I take it that you have not been a consultant to any drug or device manufacturer; is

that correct?
A That is correct.
Q And that you have not been engaged in the determination as to whether or not a 510(k) is necessary to be filed; is that correct?
A Yes.
Q That you've not before being engaged by plaintiffs' counsel in this litigation ever prepared a 510(k)?
A That is correct.
Q Before being engaged in this litigation, had you ever reviewed a 510(k)?
A No.
Q Before being engaged in this litigation, had you ever reviewed any of the different analyses done, such as the failure mode evaluation analysis or device design safety analysis, on any product?
A No.
Q Had you ever reviewed any adverse experience reports to the manufacturer?
A Yes.
Q In what capacity?
A When I was the program director of the pelvic floor disorders network.
Q I want to come back to this, but as I kind

of appreciate your CV, as the program director there, you kind of were the coordinator of certain clinical trials done by the network?
A Not the coordinator. We had a data coordinating center. That was their job. I was the program director.
Q Well, tell me what that means as program director. What did you do?
A Well, I ran the network. So I organized and led the meetings that we held initially monthly and then quarterly. I worked with the investigators in designing and -- obviously they were performing the trials at their sites, but the data coming in, the adverse events for different trials, we had safety committees consisting of investigators and members of the data coordinating center and myself. Shall I go on?
Q Well, I'm going to come back to that. Let me see if I can stick with the adverse experience reports that we were talking about. In that context you would see adverse experience reports that were adverse events that took place in the context of the clinical trials; correct?
A Correct.
Q And those reports that you received in the

context of a clinical trial might or might not have anything to do with a device; correct?
A Correct.
Q Can you tell me what trials were conducted by the network that involved the use of a device?
A We performed a placebo-controlled trial using a drug product, which is Botox, and in that context reviewing the adverse events that were submitted to the FDA and to the manufacturer.
Q Any other product that you reviewed the adverse events for?
A No.
Q No devices that you reviewed the adverse events for?
A Correct.
Q And I take it that you have never had a position where you actually went in and examined the documents or database of a device manufacturer's adverse experience reports?
A Correct.
Q And I take it that prior to being engaged in this litigation, there's never been a time at which you were in a position where you had to determine whether or not an adverse event was reportable to the FDA under the device regulations?

A That's correct.
Q Prior to becoming involved in this litigation, did you ever have an occasion to examine the MAUDE database of the FDA?
A Yes.
Q In what context?
A In the context of experiences that we had related to another trial we were running, which was abdominal sacrocolpopexy, in terms of mesh and suture complications.
Q And when was that?
A Perhaps in 2005-2006.
Q Let me just put it into context. Were you still at the Kerry Magee Hospital at the time?
A Magee-Womens Hospital.
Q I'm sorry.
A As I told you, I left Magee-Womens Hospital in May 2006, so chances are.
Q Well, I mean, I was trying to help you see if you could put dates around it a little bit. That's --
A It doesn't --
Q It helps me sometimes to remember where I was when something happened in order to put a date around it. That's the only reason I was asking.

A My work at NIH was continuous. So, no, I'm sorry, that doesn't help me.
Q Okay. Can you tell me about that trial that involved abdominal sacrocolpopexy? Did I understand you to say it was -- no. That was Botox. Just tell me about that trial.
A Yes. This was a randomized trial comparing women who were undergoing abdominal sacrocolpopexy without preoperative stress incontinence symptoms to determine if the addition of a Burch colposuspension at the time of the abdominal sacrocolpopexy could help prevent stress incontinence.
Q And what was the outcome of that study? What were your conclusions?
A The Burch was helpful not in 100 -- it did not 100 percent prevent the development of stress incontinence after abdominal sacrocolpopexy, but it was helpful.
Q And you indicated that in that context you were required to review the FDA MAUDE database?
A Yes.
Q Tell me about that.
A We were -- the patients at the investigative sites were experiencing some mesh

erosions that the investigators wondered whether this was a particular combination of mesh with a particular combination of sutures. So we were looking to the MAUDE database to see if we could gather any information if anyone else's experience had indicated that.
Q Can you tell me what types of sutures were being used?
A I don't remember.
Q Was there a particular type of mesh that was being used?
A I don't remember.
Q Do you remember whether the protocol for the trial required the use of a particular mesh in the surgery?
A No, it did not.
Q So you might have had surgical meshes used or manufactured by several different manufacturers?
A That is possible.
Q And presumably they could also be different types of meshes, partially absorbable, nonabsorbable?
A No. I believe the protocol required nonabsorbable mesh.
Q Was that the CARE study?

A Yes.
Q Do you remember what the exposure rate was?
A Not off the top of my head.
Q Did you ever publish the exposure rate?
A It should be in the document, the article reporting the primary outcomes of the trial.
Q Do you know who the lead author would be on that study where would you expect to see it?
A Linda Brubaker.
Q Tell me how you reviewed the MAUDE database at that point in time.
A I don't remember a lot of specifics. I believe we searched for mesh in the use of prolapse surgery.
Q You don't remember actually doing a search relating to, for example, one particular manufacturer reporting rates, you just looked at the entire database and did that search?
A Correct.
Q Do you remember what your findings were?
A I don't.
Q Did you speak with anyone at the FDA about this?
A No.

Q Have you ever been employed by the FDA?
A No.
Q Have you ever been a consultant to the FDA?
A No, no.
Q Have you ever served on any of the FDA advisory committees?
A No.
Q Have you ever testified at any FDA advisory committee?
A No.
Q Have you ever testified before any other government institution, any type of hearing?
A No.
Q Before being retained in this litigation, had you ever had any discussion with any of the employees at Ethicon about pelvic mesh?
A No.
Q Had you ever had any discussions with any of the employees at Ethicon about transvaginal tape?
A No.
Q Do you know Piet Hinoul?
A No.
Q Do you know David Robinson?
A I may have met him at one point in the

past. I don't remember clearly.
Q Do you know Axel Arnaud?
A No.
Q Have you ever had any involvement with the TVM group in France?
A No.
Q Do you know any of the members of the TVM group?
A No.
Q Just so I'm clear, you don't know Dr. Cosson or Dr. Jacquetin or Dr. Debodinance or any of the people that were involved in the development of Prolift®?
A Correct.
Q I take it if you don't know them, you've never spoken with any of them about their studies of the product?
A Correct.
Q Do you know Vincent Lucente?
A Yes.
Q How do you know Dr. Lucente?
A By attending the same meetings.
Q Those would be the urogynecology national meetings, professional organizations?
A Yes.

Q Do you know him and had any other dealings with him in any other context?
A No.
Q Have you ever spoken with Dr. Lucente about his use of pelvic mesh in pelvic floor repairs?
A No.
Q Do you know Dr. Dennis Miller?
A No.
Q Do you know anyone who was involved in the clinical studies for Gynemesh® PS?
A Yes.
Q Who would that be?
A I don't remember all their names off the top of my head. I know Doug Hale was involved, I believe. I know him.
Q And how do you know him?
A Attending the same meetings.
Q Do you know anyone who was involved in the clinical studies on Prolift®?
A To which studies are you referring?
Q Any of them.
MR. SLATER: Objection; overbroad.
You can answer.

BY MS. JONES:
Q I mean, really I'm just asking you to tell me anybody that you know of that was involved in the clinical studies -- not that you know of but that you know who was involved in the clinical studies involving Prolift®?
MR. SLATER: You're just having her go off the top of her head from her recollection without having any of the studies in front of her for the record.
You can do the best you can to answer.
THE WITNESS: The only other person I can think of right now is Cheryl Iglesia.
BY MS. JONES:
Q And how do you know Dr. Iglesia?
A Attending the same meetings.
Q Have you ever had any discussion with Dr. Iglesia about studies involving -- or her study involving Prolift®?
A No.
Q Have you had any discussion with Dr. Hale with respect to the study involving Gynemesh® PS?
A No.
Q Do you know any of the physicians who have

been involved in the studies of either Prolift+M® or Prosima®?
A Again, off the top of my head, the only one I know who was involved in Prosima® was Halina Zyczynski.
Q And have you spoken to Dr. Zyczynski about that?
A No.
Q Was she at Pittsburgh when you were there?
A Yes.
Q Have you had any discussion with her about the use of mesh in pelvic floor repairs in general?
A We may have discussed that when we were on the faculty together. I don't remember specifically.
Q When you were on the faculty there, was mesh used in pelvic floor repairs?
A I don't believe so. If you're -- can I clarify? Are you talking about stress incontinence or prolapse?
Q Well, let's separate it. Was it used in the context of stress incontinence?
A Other surgeons, yes.
Q You did not use it?
A Correct.

Q But other surgeons used, for example, the TVT® products?
A I don't know specifically.
Q Was mesh used in abdominal sacrocolpopexy? You know what I'm saying.
A Yes.
Q I apologize. I have for some reason a very difficult time with that word.
Did you use mesh in the context of abdominal sacrocolpopexy?
A Yes.
Q Did you have a preferred manufacturer for that mesh product?
A No.
Q Do you know whose mesh you used?
A I don't.
Q Was all of the mesh used at the Kerry Women's Hospital purchased by the hospital?
A Magee-Womens Hospital; yes.
Q And Magee-Womens Hospital would purchase that mesh and all doctors would use the same mesh?
A I don't know.
Q You don't know whether or not doctors requested, for example, the mesh of a particular manufacturer for their use in surgery?

A I don't know.
Q You did not?
A I did not, no.
Is this a good time for a break?
MS. JONES: Sure.
MR. SLATER: Sure. Take a break whenever you need.
THE WITNESS: Good.
(Short recess.)
BY MS. JONES:
Q Doctor, have you ever discussed the use of transvaginal mesh for use in pelvic floor surgery with anyone at the FDA?
A No.
Q Have you ever submitted anything about your opinions on the use of transvaginal mesh for pelvic floor prolapse to anyone at the FDA?
A No.
Q Other than the reports that you have submitted in this lawsuit, have you ever prepared any other report or writing on the use of mesh in pelvic surgery that's not identified in your CV?
A No.
(Exhibit No. 1218 was marked for identification.)

BY MS. JONES:
Q Let me show you what's been marked as Exhibit 1218 to the deposition, which is the notice for the deposition. Have you seen this document, Doctor?
A No.
Q It asks that you bring with you certain documents and materials. Have you brought any documents with you to this deposition?
MR. SLATER: One second. Just for your benefit, because I had an interaction with other counsel for the defense -- we have teams of people we deal with -- I had addressed these deposition notices and the requests directly to other counsel and had explained what we were going to produce in connection with each of the depositions, and I've been adhering to that, which was the financial disclosures, the reports obviously and the lists of materials reviewed, and had made it clear we weren't going to be producing anything else because we felt that primarily the documents are Ethicon documents that both sides have electronically stored anyway. It would have been a tremendous amount of wasted paper and duplication. So I had explained that to counsel a while back when

the requests for production from each of the experts had come out. So I didn't, frankly, even give the notice to my expert because obviously it's beyond her expertise to decide what to produce. So those were decisions of counsel.

MS. JONES: I understand.

BY MS. JONES:

Q What I want to do is to talk about this notice a little bit, Doctor, and talk with you about what we've asked for and what you have reviewed. I received on Friday, I think, it may have been Saturday, a supplemental list of materials that you have reviewed that I think -- and I'm directing this as much to counsel as to you -- I think represents the universe of materials that you have reviewed as of that date, and then I got a note that you've since looked at Dr. Lucente's deposition.

MR. SLATER: Right. What we've done, for the benefit of counsel, is -- obviously there's a tremendous amount of documents referenced, many notes and in the context of the reports that have been served. Dr. Weber's also endeavored to make a list of what she reviewed. So the entire universe would be anything referenced in the reports, anything listed in the materials reviewed list. And

I've told my associates now since we're here I want them to sweep and make sure they haven't missed anything. And, if necessary, I'll give you today again if there's anything else to be added so you'll have everything. I think you have it all, but if you don't, if there's a few stragglers, I'm going to make sure you have them.

BY MS. JONES:

Q Did you review anything, Doctor, other than what was sent to you by plaintiffs' counsel?

A Yes.

Q Tell me what that was.

A It's on the list. It would include things that I found on the FDA home page, for example, the summary statements for products.

Q Can you just describe for me what independent research you did other than review the materials that plaintiffs' counsel sent to you?

A Well, for example, if I came across a reference to a product that I wasn't familiar with or didn't already have documentation on, I would look to the FDA database to obtain the summary statement, which contains the indications and so on.

Q When you say you would look at the FDA database, you would look at the FDA website?

A Yes.

Q For information about products?

A Yes.

Q Anything else that you looked at the FDA website about?

A I looked at the advisory panel meeting that they held in September of last year -- last year, yes.

Q Other than looking at the FDA website for that type of material, did you look at or did you do any other independent research?

A Another example would be looking on the Ethicon website to see what they had available on their products, what was listed as their current instructions for use, current material directed at patients, things like that.

Q Okay. What else?

A I would often look at the medical literature when an area came up that I didn't feel I had enough background on, find relevant articles, and then they would be produced for me.

Q So you would do, for example, a Medline search for articles on a certain topic and then ask plaintiffs' counsel to send you the actual articles?

A Yes.

Q And can you tell me what those topics were that you asked for articles on?

A Those are listed in the materials reviewed, the articles themselves.

Q But what I'm asking you is you said that there were areas that you did not feel as knowledgeable about and did research on. I'm asking you to tell me what those areas are.

MR. SLATER: Objection to the form. You can answer.

THE WITNESS: Hernia repair, complications and effectiveness of stress incontinence products. That's what I can think of off the top of my head.

BY MS. JONES:

Q Have you spoken with any of the plaintiffs in this litigation?

A No.

Q You have reviewed the medical records of Ms. Gross and Ms. Wicker; correct?

A Yes.

Q Have you reviewed the medical records of any other plaintiff?

A Yes.

Q How many?

A Approximately 10 to 15.
Q Have you prepared reports on any of those women other than Ms. Gross and Ms. Wicker?
A Yes.
Q Can you tell me the names of those women?
A Donna Rogers and Patricia Firman, F-I-R-M-A-N.
Q Anyone else?
A No.
Q Had you spoken with the treating physicians or surgeons of any of the plaintiffs in this litigation?
A No.
Q And I assume you've not spoken with any of their family members, husbands or significant others or anything of that nature?
A Correct.
Q Other than Mr. Slater, what lawyers have you met with in the context of this litigation?
A No one else.
Q In fairness, I know you said that you were contacted and talked with somebody else in Mr. Slater's office, but you've not talked with anyone that's not associated with Mr. Slater's office here; is that correct?

A Correct.
Q Have you attended any meetings in which other expert witnesses were present?
A No.
Q Have you participated in any phone calls with other expert witnesses for the plaintiffs?
A Yes.
Q And was that on more than one occasion?
A No.
Q With whom did you speak?
A With Dan Elliott.
Q Have you spoken with any of the other witnesses --
A No.
Q -- for the plaintiffs?
A By e-mail.
Q Let's see if I can separate these. When did your conversation with Dan Elliott occur?
A On Saturday.
Q Two days ago?
A Correct.
Q And can you tell me what the subject of that conversation was?
A The case.
Q What about the case?

A We were specifically discussing the urologic aspects from Dr. Elliott's standpoint and the urogynecologic aspects from my standpoint.
Q Was that related to a specific plaintiff or just in general?
A Both.
Q Well, what I'd like you to do is tell me everything you can remember about that conversation.
A We were discussing the urinary retention issue, and we discussed the contraindication that now exists for patients with preexisting pain conditions.
Q Was anyone on the telephone besides you and Dr. Elliott?
A Mr. Slater.
MR. SLATER: I was teaching them.
BY MS. JONES:
Q How long did that phone call last?
A I was on the phone call for approximately half an hour.
Q And when you said that you were discussing contraindications of pain syndrome, tell me what you remember about that discussion.
A The knowledge that has been gained since the Prolift® product and procedure was marketed that

women who have a preexisting pain condition are relatively or absolutely contraindicated from undergoing a Prolift® procedure.
Q And when you say that, it's based upon what?
A Upon their higher risk of exacerbation of their existing pain condition or the development of a new pain condition.
Q And were you giving that information to Dr. Elliott or vice versa?
A We were discussing it.
Q Well, can you tell me in what context you were discussing it? Were you talking about it in the context of a specific plaintiff?
A Yes.
Q And who was that?
A The plaintiffs Linda Gross and Pamela Wicker.
Q Did Dr. Elliott express any opinions to you about that?
A Yes.
Q What were those?
A I'd rather you ask him.
MR. SLATER: She's allowed to ask you.

BY MS. JONES:
Q I'm entitled to ask you.
A You're entitled to ask me. All right. All right. His opinions, as I recall, were that the urinary retention that Linda Gross experienced was a direct result of the Prolift® procedure. And the fact that Pamela Wicker had preexisting pain conditions in her interstitial cystitis and her migraine headaches is a contraindication to her having undergone the Prolift® procedure, which is known now.
Q Did Dr. Elliott express an opinion to you as to whether or not at the time that Ms. Wicker received her Prolift® that information was known?
A That information was foreseeable by Ethicon. They did not warn physicians and patients of that likelihood.
Q My question was a little bit different. It was whether or not it was known. Had it been published in the medical literature?
A It was not at the time that the plaintiffs underwent their surgery.
Q Now, you said that those were the opinions that Dr. Elliott expressed to you. What opinions did you share with him, if any?

A I agreed with his opinions.
Q My recollection is that you said, Doctor, that you were discussing with him and you shared with him information, facts, opinions, whatever, from the urogynecological standpoint and he was, as I recall what you said, expressing opinions to you from the urological standpoint; am I right?
A Yes.
Q How did those differ in terms of -- what information were you sharing with him from the urogynecological standpoint?
A The two different specialties have a lot of overlap. They also have their different perspectives. And I think by discussing our perspectives and our opinions that, for example, urinary retention in Linda Gross was caused by the Prolift® product and procedure, that he professed that opinion on the basis of his urologic training and experience and I professed that opinion on the basis of my urogynecologic training and experience.
Q Did the two of you reach those opinions by approaching the subject from different viewpoints?
A From the perspective of our differing specialties, yes.
Q What I'd like for you to do then is to

tell me what the difference is in terms of the way you approached it from the way he approached it. What facts, what knowledge, whatever that you had from the urogynecological spectrum did you use to educate him, if so, and vice versa?
MR. SLATER: Objection. The foundation of the question assumes aspects -- it's just not accurate foundation.
You can answer as best you can and tell her what went on during the conversation.
THE WITNESS: I can answer from my perspective as a urogynecologist. I cared for women exclusively. My training has been in the care of women exclusively. My experience may be broader in the care of women with prolapse -- I don't know that for a fact -- regarding Dr. Elliott's practice. So my experience, my training and experience, in caring specifically for women with pelvic floor disorders gives me the background to interpret the clinical events and that's the basis for my opinions.
BY MS. JONES:
Q Did Dr. Elliott share with you any insights that you had not previously had?
A No. I'd like to expand on that a little. I think he has a greater experience in caring for

women and men perhaps with interstitial cystitis and that that may give him greater insight into the complications that Pamela Wicker has experienced and also into the possible diagnosis that Dr. Benson attributed to findings at the time of a cystoscopy with Linda Gross after her Prolift® surgery.
Q Other than Dr. Elliott, have you spoken with any of the other expert witnesses identified by the plaintiffs in this case?
A No.
Q When you reviewed Ethicon documents or the literature in this case, did you take any notes?
A Yes.
Q And where are those notes?
A On my computer and handwritten.
Q But you did not bring those with you?
A No.
Q Did you separately mark in any way on the documents?
Let me ask this first: Did you receive those documents electronically or in hard copy?
A Both.
MR. SLATER: I just want to place an objection. I'm generally not somebody who overobjects during a deposition and I don't mind

making a record, but to the extent that -- and I think it was essentially exclusively -- what Dr. Weber was doing was part of her interaction with me and part of our work product, I'm not necessarily going to agree to produce these things. I don't mind you setting a record because I know you want to find out what exists, but a lot of this may come within the work product privilege.

MS. JONES: Okay. I don't think her notes come within the work product privilege and how she maintained them and did that.

MR. SLATER: To a large extent, it also may come within drafts of different portions of the report. It's extensive.

MS. JONES: Well, we'll take that up and deal with it. I mean, I understand that we're not entitled to drafts and all, but my understanding, from what Dr. Weber suggested, was that she simply had notes that she had taken from review of the documents. I do think we're probably entitled to those.

MR. SLATER: We'll address it.

MS. JONES: That's fine.

MR. SLATER: It becomes a two-way street, you know --

MS. JONES: We will address it.

MR. SLATER: -- that I'm generally not that interested in driving down, but we can talk about it.

BY MS. JONES:

Q I forgot, Doctor, to ask you, you told me that you had also communicated with other experts I think by e-mail?

A Yes. Generally, that would be a three-way conversation with Mr. Slater by e-mail.

Q And who else?

A Oh, Sue Shott.

Q And when did those conversations or communications take place?

A I don't recall exactly.

Q Have you met Sue Shott?

A No.

Q Have you ever had any occasion to work with or familiarity with her work before?

A I know of some of her medical literature. That would be the extent of my...

Q And can you tell me when you had these e-mail communications with her?

A No, I don't recall.

Q Was it recently?

A What do you mean by "recently"?

Q Within the last month?

A No.

Q Was it before she produced a report?

A She has also more than one report. To which report are you referring?

Q Either one.

A The best I can do is over the last several months, but not in the last month.

Q Can you tell me what the subject matter of those communications was?

A We were discussing the Gynemesh® PS mesh study and the TVM studies.

Q Do you have copies of those e-mails?

A Yes.

Q You didn't bring those with you today either, did you?

A No.

Q Counsel and I will address these issues later on, but I'm going to ask that you maintain all of your notes and all of your correspondence until we resolve the issue as to whether or not we're entitled to them. Okay?

A Yes.

Q Have you had correspondence with any of

the other experts?

A No.

Q Do you personally know any of the other expert witnesses?

A I know Dr. Margolis.

Q How do you know Dr. Margolis?

A Attending the same meetings.

Q But you've not discussed this litigation with him?

A No.

Q Anybody else?

A No.

Q You obviously are being compensated for your time in working with plaintiffs' counsel; correct?

A Correct.

Q Can you tell me at what rate you're being compensated?

A It is $350 an hour.

Q And is that for all purposes?

A Yes.

Q It's not more for testifying versus review of documents, preparing reports or anything?

A We haven't discussed that.

Q As we sit here today, all of your time has

been billed at $350 an hour?
A Earlier in our working relationship it was $250 an hour.
Q Can you tell me approximately when you changed the rate from 250 to 350?
A Perhaps the spring of this year.
Q 2012?
A I believe so.
Q How much have you been compensated at this point?
A I don't know.
Q You didn't bring your financial statements with you?
A I understood from Adam that that had been disclosed.
MR. SLATER: You have our disclosures. They didn't give that to you?
MS. JONES: I have not seen them.
MR. SLATER: I'll have somebody print a copy. We produced them for all our experts. The hours spent, the rates, when the rate went from 250 to 350, the whole thing was produced.
MS. JONES: Okay. I apologize. If I have --
MR. SLATER: It's no big deal.

MS. JONES: It's either it never got to me or I've overlooked it.
MR. SLATER: And I told defense counsel that I served it on, which was not you in fairness, I don't expect anything else from the defense. I expect similar disclosures.
BY MS. JONES:
Q Can you tell me, Doctor -- and maybe we can get this sometime in the next day or two --
MR. SLATER: I can get it for you by the next break.
MS. JONES: That's fine.
BY MS. JONES:
Q Can you tell me approximately how much time you've spent?
A It varies.
Q Let me ask you this: You have produced a voluminous report, general report, in this litigation. Can you tell me how long it took you to prepare that?
A I've been reviewing documents since February of 2010. I've been working on writing the report since perhaps 2011. It's been a -- not a continuous process but a process of evolution.
Q Was there a point in time that you

specifically sat down and said I'm going to start drafting my report?
A I don't remember.
Q Did you submit statements to counsel for your time?
A Yes.
Q When you would submit those statements to counsel for your time, would you itemize what you had done?
A I have done that recently. I hadn't done that for the entire course of...
Q When you say you would itemize what you had done, give me an example of how you would itemize it.
MR. SLATER: I'm going to preserve my objection. I'll let her answer the question, but I'm not waiving any objections to work product.
You can answer.
THE WITNESS: I would make a table. The first column has the date, the second column has the tasks, and the third column has documents produced. And what I mean by that is documents that I myself have written that I'm submitting to Mr. Slater.

BY MS. JONES:
Q Have you written documents for Mr. Slater other than drafts of this report?
MR. SLATER: Don't answer the question.
She's not going to testify about drafts. Remember, we've served multiple supplemental reports, so --
MS. JONES: I thought I made it clear that I wasn't asking about drafts. I'm asking whether or not there has been anything else prepared that are not drafts.
MR. SLATER: My position is whatever my expert's been providing to me is work product. Because she may not understand the difference and may make a mistake in how she speaks about it, I'm just not going to have her testifying about what she provided me. My position is what she was providing to me were draft reports, formulations of draft reports. And that's my position.
BY MS. JONES:
Q Have you sent any written documents to anyone other than Mr. Slater?
MR. SLATER: When you say "Mr. Slater," you mean me or my associates

obviously; right?
MS. JONES: Yeah.
THE WITNESS: No.
BY MS. JONES:
Q Have you met any of the other plaintiffs' lawyers involved in this litigation?
A No.
MR. SLATER: In fairness, the guy you met today is a plaintiff lawyer.
THE WITNESS: Oh.
MR. SLATER: Jeff Grand is a plaintiff lawyer.
THE WITNESS: Oh, I beg your pardon.
MS. JONES: Just for the record, so that the record is clear, the notice of the deposition is marked as Exhibit 1218.
BY MS. JONES:
Q Have you provided any written documents to counsel other than drafts of your report and invoices?
MR. SLATER: My position is the same. That was the question you asked. I'm taking the same position. You're not asking like did she send me a medical article or something, you're talking about things that she authored; correct? I mean, I

have no problem with you asking did she ever send me an article or something she found, but in terms of things that she wrote, my position is that's work product, that's my interaction with my expert. And I would accord you the same position as well.
BY MS. JONES:
Q Have you sent to Mr. Slater information that you gleaned from any independent research?
A For example, if I came across an article in medical literature that I wasn't sure Adam had seen yet, I would forward it to him.
Q Have you sent anything other than medical articles to him?
A I can't think of anything else right now.
Q Have you given any interviews about this litigation?
A No.
MR. SLATER: About the litigation in particular?
MS. JONES: Uh-huh.
BY MS. JONES:
Q When is the last time you gave an interview about pelvic mesh?
A I believe it was last fall.
Q And to whom did you talk?

A Rachel Zimmerman.
Q Other than Rachel Zimmerman, have you given other interviews relating to the use of mesh in pelvic surgeries?
A No.
Q Have you ever given any interview on TV or film or anywhere where you've appeared personally?
A No.
Q Have you participated in any clinical trials since you left Magee in 2006?
A I continued to work with NIH until 2008.
Q And you were the program manager there; correct?
A Yes.
Q But in terms of actually performing the surgery or prescribing the Botox, for example, that was done by doctors in the network and not you; am I right?
A Yes.
Q Have you written anything, Doctor, about mesh that's not shown on your CV, other than obviously the reports in this litigation?
A Written for publication do you mean?
Q Well, written for publication, yes. Have you written anything for publication that's not on

your CV?
A No.
Q Have you written anything that has been submitted to any third party that's not on your CV?
A No.
Q Let me give you an example. You've never written anything to any of the medical schools or training programs with respect to your opinions on mesh?
A No.
Q I think you've already said that you had not submitted anything to the FDA, for example?
A Correct.
Q Am I correct, Doctor, that you never used or implanted Prolift®?
A That is correct.
Q Am I correct that you never used or implanted Gynemesh® PS?
A That I can't say for sure since I am not sure what mesh I used in abdominal sacrocolpopexy.
Q Did you ever use any mesh that you actually cut and modified into shape in the course of your surgeries?
A Are you referring to transvaginal placement?

Q Well, let me just see if I can do this. Did you ever perform any transvaginal placement of mesh in any surgery?
A Yes.
Q What types of surgery did you perform involving transvaginal placement of mesh?
A TVT®.
Q And when you used the TVT®, did you use Ethicon's TVT®?
A Yes.
Q And can you tell me when you began using Ethicon's TVT®?
A When I was at the Cleveland Clinic. That was just beginning to be available.
Q My recollection is that TVT® became available in 1998. Would you have been using it about that time?
A No, I don't think so. I think it would -- my recollection it is closer to the time I left the clinic. And then when I joined Magee-Womens Hospital, I did not use TVT®.
Q Had you used anything before you used TVT®?
A In terms of a mesh product --
Q Yes.

A -- for stress incontinence? No.
Q Do you have any recollection of using any sling product other than a TVT® for urinary incontinence?
A No.
Q At any time?
A No.
(Exhibit No. 1219 was marked for identification.)
BY MS. JONES:
Q I'm going to show you, Doctor, what I've marked as Exhibit 1219, which is a copy of your CV that we were provided. I'd like to ask you whether or not this is current.
A Yes, this is current.
Q Do you have any publications that are in process?
A No.
Q You don't have any that you've submitted, for example, that you're waiting to hear on acceptance?
A Correct.
Q What I want to do is talk with you about your CV a little bit. We covered some of this so I'm going to jump around a little bit. Just bear

with me.
If we look at your professional experience, you show on there 2008 till present the International Academy of Pelvic Surgery. And we've already spoken about that. As I recollect and understand, your role is to summarize, if you will, the current medical literature on urogynecology?
A Let me clarify. I select a topic when -- once I've looked at the medical literature and if an article of interest has been recently published, I may select that and then a handful of other articles on that topic. So it's theme-based. And then I critically review the articles I've selected and provide a summary and a clinical take-home message for the audience.
Q Do you do that once a month?
A Once a month.
Q And when you say that you provide the clinical information and take-home article, that would be written and posted on the website?
A Correct.
Q And are those writings and opinions attributed to you specifically?
A Yes.
Q So if we do a search, for example, of the

website, we would be able to find all of the comments that you had written over a period of time?
A Yes. And I would like to add that you won't find anything for the past two or three months because I have devoted my time to preparing for this and the trial. So I haven't done it continuously except for the past two or three months.
Q When you said you devoted yourself to preparing for this and the trial, what have you done?
A I've continued to review documents. I've read deposition testimony. I have continued to produce the supplemental reports. I've read the reports of the defense and plaintiffs' experts.
Q And I know that we're going to get presumably the disclosure here, but can you tell me on a just daily or weekly basis how much of your time that's taken?
A It varies. Would you like to restrict that to a time frame and perhaps I can answer you more accurately?
Q Well, you said that the last two or three months you had devoted most of your time to working on this case. And I'm just trying to get a sense of whether that's 40 hours a week and you're working,

you know, a typical day or it's, you know, three hours one week and 40 hours the next week.
A I would say over the last couple of months it's been more steady. Let me think for a minute and I'll do my best to give you a weekly estimate.
I would estimate a range of between 25 to 30 hours a week.
Q Other than these review articles, themes that you write for the International Academy of Pelvic Surgery, have you written other materials for that group?
A No.
Q You also show that you were a freelance editor for The Medical Editor. What is The Medical Editor?
A That is a service run by Carl Richmond, as you can see, who accepts typically manuscripts from scientists all other the world who pay for editing services to improve the clarity, the grammar, the spelling, make it consistent with the journal's requirements.
Q And as a freelance editor for that group, I assume that the way it would work is periodically they would send you a paper and you would edit it and send it back?

A Correct.
Q In the course of that, was it limited to any particular field?
A No.
Q So this is not necessarily urogynecology-related?
A Correct.
Q How many papers approximately have you edited for The Medical Editor?
A Hundreds.
Q One hundred?
A Hundreds.
Q Hundreds. I take it that you no longer do that?
A Correct.
Q How were you compensated for that? Were you on a salary? I assume as a freelance editor you were compensated on the basis of each paper?
A Hourly.
Q So if it took you ten hours to edit, you would be paid a certain amount by the hour?
A Correct.
Q And when you say that you had done hundreds, was that essentially a full-time position?
A Perhaps not full time. Perhaps

three-quarters time.
Q Let me see if I can put it in this perspective. When you say "three-quarters time," does that mean that you might be spending as much as 30 hours a week doing that?
A Correct.
Q And during that same period of time, you also have listed BioScience Writers. Were you doing the same thing for that group?
A Similar. A wider range of documents. When I was working with The Medical Editor, that was almost exclusively academic manuscripts. The documents with BioScience Writers was a wider range of documents.
Q When you're talking about academic manuscripts, are you talking about the manuscripts that are being written by academicians or are they written for academicians?
A Both.
Q How do you define academic manuscripts?
A A manuscript that's intended to be published in a peer-reviewed publication.
Q And I take it then that the BioScience Writers might or might not be headed for peer-review publication but perhaps would be for some popular or

industry trade publication?
A Not necessarily, not necessarily for publication. Grant applications, things like that.
Q And, again, it would not be limited to urogynecology?
A Correct.
Q In none of these positions after 2007 up to date have you been engaged in doing any original research; is that correct?
A The last publication I have in terms of original research was published last year, in 2011. So that was something I was involved in leading up to 2011.
Q Well --
A Can I correct something? Because I realize I've been speaking of my time at NIH as if it went through 2008, but it really ended at the end of 2007 before going into 2008.
Q Okay. What is the publication that you're referring to in 2011?
A It's on Page 6 of 25, the first one.
Q This is the reanalysis of the randomized trial?
A Correct.
Q That randomized trial was actually done

about 2000, wasn't it?
A Approximately.
Q I'm not sure exactly. My recollection is that you published the results of that in 2001; is that right?
A I think that's correct, yes.
Q So the trial itself was actually conducted in the late '90s, early 2000?
A Correct.
Q And this reanalysis was done after you were retained as an expert in this litigation?
A Correct.
Q Have you published other materials since you were engaged as an expert in this litigation?
A In the nonpeer-reviewed literature, yes.
Q Can you identify for me what those publications are?
A Page 13 of 25. These are in reverse chronological order so that would be, let's see, I guess just the first two.
Q Do you remember whether or not you had already been contacted by plaintiffs' counsel when you wrote commercial pressures and professional ethics revisions to the ACOG practice bulletins?
A I don't remember.

Q You certainly by the time that you had written that had addressed and made comments with respect to lawyer advertising with respect to pelvic mesh surgeries, hadn't you?
A I'm sorry?
Q By this point in time you certainly were aware and eventually wrote about lawyer advertising related to the use of mesh in pelvic floor repairs, didn't you?
A I'm not familiar with what you're referring to. Can you show me that?
Q We might get to it. You don't remember that?
A I said I'm not familiar with what you're referring to.
Q You do remember seeing lawyer advertising with respect to mesh being used in pelvic floor repair surgeries, don't you?
A Yes.
Q And that you saw that early on after the 2008 public health notice?
A I don't remember specifically.
Q If we look at the next entry on your CV where you said you were medical officer or the program director for research for female pelvic

floor disorders, how did that come about? I mean, how did you get involved with that program?
A In the late 1990s the professional organizations, the leaders of our professional organizations, met with the leaders at NIH to discuss the lack of high-quality research in female pelvic floor disorders. And with that encouragement NIH created a position in the National Institute of Child Health and Human Development to develop a specific research program devoted to female pelvic floor disorders. And at one of our professional meetings the director of the NICHD at that time, Duane Alexander, came and spoke to the group and announced that this position was available. So I applied and I was selected.
Q Were you in the group that went initially to discuss this program with the NIH?
A No.
Q Do you know who was?
A The only person I can remember is Richard Bump.
Q As I recall, what you said was that the leadership of the professional organization went. Was that the leadership of ACOG or was it --
A No, not ACOG. I believe it was the

American Urogynecologic Society and the Society of Gynecologic Surgeons.
Q And when you were selected to run that program, what instructions were you given by the NIH in terms of what they expected, what was going to be done?
A They wanted to develop several initiatives to solicit investigator -- I'm sorry -- to solicit applications from investigators in the field. Because there hadn't been dedicated NIH funding for female pelvic floor disorders in the past, investigators would have a very high level of competition to obtain NIH funding. So part of my job was to develop these initiatives to solicit applications from the investigators in the field to let them know that NIH is concerned about the lack of high-quality research in this field and is dedicating research funding to advance the science. And those are called requests for applications. And they're posted with a deadline. And then the applications come in, are reviewed, and depending on the limits of the funding, several are selected for funding.
So we had an initiative focused on basic science research in female pelvic floor disorders,

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epidemiological research, and then for clinical research we established the clinical trials network, the pelvic floor disorders network, which also went out as a request for applications specifically for the investigative sites and also for the data coordinating center for investigators to submit applications and be selected for participation.

Q And the way I understand NIH works is you post, for example, a request for application and then an investigator, a doctor, would submit a proposal in which he says I'd like to do a study, basically submits the protocol or grant request, I'd like to do a study involving these issues, these number of patients, and this outcome, and the NIH and then presumably you would look at that proposal and protocol and say this looks like a good study and I'm going to give him the money to conduct it?

A It's a little --

Q I know that's simplified.

A Yes.

Q But am I essentially correct?

A The main difference is the review committee is independent of the NIH staff. There are standing committees and then for the RFA specifically we call an ad hoc committee to review

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the applications, they're scored, and then based on the score is the typical way that funding decisions are made.

Q All right. So you didn't yourself then personally make those funding decisions?

A Correct.

Q You had an ad hoc committee that would have reviewed all of them and decided which ones would be the most appropriate for funding?

A Yes. As I said, they would score them and then obviously we would rank them by score. We have input, depending on what we see as the greatest need in the field, but generally the funding decisions go very strongly by score.

Q And then once a study is funded, you as the program director would monitor that study and receive reports, interim reports, in the context of the study?

A Correct.

Q You note on your CV that you were involved with the investigational new drug trial. Is that the Botox --

A Correct.

Q -- trial you referenced earlier?

A Yes.

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Q And when you noted that you were the clinical monitor, that you would review adverse reports, you obviously were not a blinded investigator here, were you?

A Perhaps I misunderstood the question. With the clinical monitor, who is one person, and the safety monitor, who is another person, from the data coordinating center, we would review the adverse events. And those were blinded. The data were blinded to us as we reviewed the adverse events.

Q Okay. And was that then a review of all of those and all of the different clinical trials that were being sponsored at the time?

A Correct.

Q When you were doing this and acting as the medical officer program director, how much time did you spend in that capacity?

A That changed over the years. When I began in 1999, it was 25 percent. And then it increased. I believe when I left Cleveland to go to Pittsburgh, it increased to 50 percent. When I stopped my surgery practice, it went to 75 percent. And then when I left Magee-Womens Hospital altogether, it went to a hundred percent.

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Q And you left the hospital in the end of 2005, so you had a two-year period that it was a hundred percent of the time?

A Close. I believe I left Magee in May of 2006.

Q I'm sorry. I think you probably said that and I --

A Yeah, in the range of a year and a half.

Q And when you said that it became a hundred percent of your time, did you spend more and more time there or was it just a hundred percent of the time because you no longer had the obligations at Magee?

A The latter.

Q So would it be fair to say that the amount of time, not the percentage of time but the amount of time that you spent as program director basically remained the same over the entire period of time?

A No, no. It increased.

Q Okay. But it didn't increase -- this is what I'm trying to say: After you left Magee, it remained the same?

A No. It went from 75 percent to 100 percent.

Q I know. I think that's where we

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miscommunicated a minute ago, because I thought you told me it went to a hundred percent of your time because you were no longer working at Magee but it didn't mean extra time. Do you see the difference that I'm saying?

A No.

Q Okay. It's one thing to say I'm spending 75 of my time on this and 25 percent of my time at Magee, but if that 25 percent of the time at Magee goes away and you're only working at NIH, then it becomes a hundred percent of the time but it doesn't necessarily mean more time. And I thought that was what you told me had happened. And I may have misunderstood.

A I am not sure what you're asking. I'm sorry.

Q All right. Let me see if I can do it this way: When you were at Magee and you said you were spending 75 percent of your time working as the program director -- correct?

A Yes.

Q -- how much time was that?

A You know, these time calculations are artificial.

Q I understand. I'm just asking for you to

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give me an estimate. You know, did you spend 30 hours a week on it?

MR. SLATER: If you can reasonably estimate it. If you find it to be a guess, she doesn't want you to just guess at something.

THE WITNESS: It would be probably in the range of 50 to 60 hours a week.

BY MS. JONES:

Q A week? That would have been what you were spending in 2005?

A No. In 2006, after I -- no, no. I'm sorry. You're correct. You're correct.

Q That's what were spending in 2005. What did you spend in 2006?

A Probably 60 to 80.

Q Bear with me. I know I'm repeating myself. When you started this, you initially were at the Cleveland Clinic; correct?

A Correct.

Q And at that point in time you were spending about 25 percent of your time there?

A Correct.

Q Did you have a contract with the NIH?

A They have a mechanism that's called IPA. What's that stand for? I don't remember what that

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stands for. But it is an arrangement between the NIH and my institution to account for a certain percentage of my time that I'm not spending working for the institution, the Cleveland Clinic at that time.

Q So the arrangement was really between the NIH and the Cleveland Clinic for your time?

A Correct.

Q And did the same thing hold true with respect to Magee when you moved to Magee?

A Correct.

Q And at that point in time it changed from 25 percent to 50 percent?

A Correct.

Q And at what point in time did it change to 75 percent?

A When I discontinued my surgical practice.

Q At the end of 2004?

A Yes, I believe that was the fall of 2004.

Q You said that you left Magee-Womens Hospital in June of 2006?

A I believe it was May.

Q And why did you leave the hospital at that time?

A I wanted to be able to devote all my time

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to the NIH work. And I can expand on that a little if you like. I came to Magee with the specific idea of developing a new fellowship program in female pelvic medicine and reconstructive surgery, which is a long name that's been given to our subspeciality of urogynecology. And I accomplished that and we graduated several fellows and it was running along very smoothly, so I felt that it was safe to carry on with the faculty that were in place and I could then devote myself to the NIH.

Q When you went to Magee, at the time that you went there, there was no fellowship program?

A Correct.

Q Did you actually have to go out and hire or retain, bring in other faculty members for that residency program?

MR. SLATER: Fellowship program?

MS. JONES: I mean fellowship program.

THE WITNESS: Not at that time. As we -- it's a three-year fellowship. So we obtained a fellow, the first fellow, in the first year, so there was one fellow; a second fellow in the second year, so there were two fellows; and a third fellow in the third year, so there were three fellows. So

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we had the full complement of three fellows.
At that time when we had three fellows, then staff were added to increase the exposure of the fellows to clinical practice and research, for example, things that were important in their fellowship.
Q Did you ever have more than one fellow per year --
A No.
Q -- in the fellowship program?
A Oh, I take that back. No. At one time we did have two fellows in one year. It occurred with a graduating resident that everyone was -- graduating from the residency at Magee-Womens Hospital that everyone was very impressed with so we decided to keep her as well as the fellow who we had already arranged to keep -- or, you know, take on.
Q And even though you were the director of that fellowship program, I assume other faculty members and other surgeons were involved in the training of those fellows as well?
A Correct.
Q In other words, you weren't the sole person that was there responsible for ensuring that they were trained?

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A Correct.
Q In the course of developing this program, though, would you be responsible for developing the curriculum, I guess, in terms of what they should be taught?
A Yes, in a specific sense. In a general sense the American Board of Obstetrics and Gynecology, which is our certifying organization, provided a general outline of the topics that the fellows should be taught. And then we filled in the specifics of exactly how they were going to obtain that knowledge.
Q And did there come a point in time at which ACOG actually certified that fellowship?
A The American Board of Obstetrics and Gynecology, two different -- yeah, ACOG is the professional organization.
Q I apologize.
A Yes.
Q And when was that?
A Let me just glance at my CV and see when we graduated the first fellow, because she came under the certification. It's a process, as I'm sure you can understand.
Okay. So our first fellow graduated in

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2004. So then I would expect we received certification in 2003. That's Page 5 on the bottom.
Q Okay. In this fellowship program, although you did not use transvaginal implanted mesh in your surgeries, did other surgeons at Magee use transvaginal mesh?
A To the best of my recollection, at or around the time I was leaving that was beginning to happen.
Q At or about the time you were leaving in 2006?
A Correct.
Q At the time that you were there, were slings being used for urinary incontinence?
A To what type of sling are you referring?
Q Well, were mesh slings being used?
A No.
Q Was any mesh used at Pittsburgh other than for abdominal sacrocolpopexy?
A Not to my recollection, except as I just said, toward the time I was leaving.
Q And toward the time that you were leaving, what were the surgeons there beginning to use?
A I don't remember.
Q Were the residents trained on how to

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perform surgeries to correct urinary incontinence?
A The fellows; yes.
Q The fellows. I'm sorry.
And what surgeries were they trained on?
A Slings.
Q What types of slings?
A Rectus fascia slings, cadaveric fascia slings, string slings.
Q They were not trained on any mesh products?
A Not to my recollection.
Q And can you tell me what training they received with respect to the other types of pelvic organ prolapse surgery?
A Yes. Abdominal sacrocolpopexy, uterosacral ligament fixation and sacrospinous ligament fixation for apical prolapse, anterior and posterior colporrhaphy for anterior and posterior vaginal prolapse, paravaginal repair for anterior vaginal prolapse.
Q And were there any procedures in place to evaluate the competencies of the fellows in performing each of those surgeries?
A Yes.
Q Tell me how you do that.

A When the fellows were on surgical rotations, each faculty member on a monthly basis -- they rotated on a monthly basis. So at the end of each month's rotation the faculty would provide to me, as the fellowship director, an evaluation of the fellows' progress in learning how to perform the surgeries.

As the fellows progressed through their fellowship and we saw them evolve in their level of skill and experience, we then arranged the surgeries in such a way that the faculty member was the second assistant, the fellow was the first assistant, and the resident, the senior resident, was the primary operating surgeon. And in that way the fellows would also learn how to teach.

Q Your fellowship program was, you've already said, certified under the American Board of Obstetrics and Gynecology; correct?

A Correct.

Q Is it a fair statement that the fellows in your program were doctors who had completed training as OB-GYNs?

A That wasn't a requirement. They could also have graduated from training in urology. Typically they are residents who applied for a

program, had graduated -- or were going to graduate from residencies in obstetrics and gynecology.

Q Did residents in OB-GYN at Pittsburgh do pelvic floor repair surgeries?

A Yes; under the supervision of the faculty.

Q So as residents they were taught, for example, to do abdominal sacrocolpopexy?

A Yes, in -- it depends on the difficulty of the case. The attending physician would make a decision as to whether that was a fellow case or a resident case or both.

Q But is that one of the surgeries that you would have expected a resident to be trained on during the course of a residency in obstetrics and gynecology?

A Again, it depends. Some residents have already decided on their future career path. They may decide to go into maternal-fetal medicine or reproductive endocrinology and infertility. And in that situation it is not a good use of surgical teaching to teach those residents how to perform that surgery. That's not going to be part of their clinical practice when they graduate.

Q Pelvic floor repair surgery is fairly complex surgery, is it not?

A Yes.

Q Regardless of the form, whether it's colporrhaphy or sacrocolpopexy, it can be difficult surgery --

A It can be.

Q -- for a doctor?

It is the type of surgery that generally is best performed in the hands of a specialist; is that fair?

MR. SLATER: Objection.

You can answer.

THE WITNESS: I wouldn't want to make an across-the-board statement agreeing with that. I think in terms of a general philosophy I would agree with that. And certainly the American Board of Obstetrics and Gynecology agreed with that since they created the subspeciality of female pelvic medicine and reconstructive surgery.

BY MS. JONES:

Q And it is the specialists, whether they come from a gynecological background or a urological background, that generally perform that surgery?

A I don't know if I can say that on a nationwide basis.

And I would like to correct one thing now

that you mentioned urology, because this fellowship was actually jointly boarded, if you will, by the American Board of Obstetrics and Gynecology and the American Board of Urology. What would typically happen in a case like ours as a urogynecologist, the American Board of Obstetrics and Gynecology would certify my program and the American Board of Urology would certify programs that were led by urologists.

Q At the time that you were organizing this fellowship in Pittsburgh, how many fellowship programs were there in the United States?

A I believe there were 17.

Q And that's 17 programs for urogynecology in general, whether it's the American Board of Obstetrics and Gynecology and the American Board of Urology?

A I believe that's correct.

Q So if there were 17 programs, for example, you would generally be training someplace between 50 and 60 fellows a year in this surgery?

A Collectively. Of course, they only graduate one at a time.

Q Right.

A Yes. But at any given moment there may be something like 50 in training at some level between

the first and the third year.
Q It's a fairly small group of folks that are trained on an annual basis?
A It's growing. It's new. But, yes, it is small.
Q Do you know how many fellowship programs there are today?
A I don't.
Q At the time that you were at Magee, from 2001 to 2004, you were spending about 50 percent of your time as the program director for the female pelvic floor disorders; correct?
A Yes.
Q And then 50 percent of your time would have been spent as the program director for the fellowship program?
A In addition to my clinical practice and my clinical research, yes.
Q And that's what I want to get to. Can you tell me how your time was broken down during that time period?
A Well, I had one day in surgery. I think I had one and a half days in the office. And that would leave, say, a half a day roughly for my responsibilities as the program director of the

fellowship.
Q When you say you had a day and a half in the office, was that a day and a half of clinical care in the office?
A Yes.
Q And can you tell me at that point was your practice here restricted to urogynecology?
A Yes.
Q And were those patients that were referred to the institution with pelvic floor disorders or urinary incontinence or other issues?
A They could be referred by other doctors. They could refer themselves in, self-referrals.
Q And we talked a little bit about your surgical practice, but there you would have had one day of surgery a week from 2001 to 2004?
A Correct.
Q And during that time do you have any idea, Doctor, how many abdominal sacrocolpopexies you performed?
A That would be relatively uncommon. Maybe, if I'm guessing six per year, three years, 15 to 20.
Q And how many colporrhaphies?
A Well, again, unusual to come across a patient who needed a single -- see, abdominal

sacrocolpopexy tends to address those things. Working vaginally doing a colporrhaphy, it would be unlikely to address all of the patient's problems so it would be a combination of procedures.
Q Is abdominal sacrocolpopexy the only abdominal surgery you performed?
A Well, for prolapse, yes.
Q Did you perform it for other conditions?
A Retropubic colposuspension, Burch colposuspension for incontinence.
Q Anything else?
A No. Oh, excuse me. Paravaginal repair can also be performed usually in conjunction with a Burch.
Q And do you have any idea during that period of time how many Burch procedures you performed?
A Well, at Magee I was more likely to perform a sling. That was the experience of the faculty group. I should add that at that time we were participating in a clinical trial that was run through the urinary incontinence treatment network, which was also an NIH-funded network that I worked with. I didn't lead that one, but I worked with them. That was funded by the National Institute of

Diabetes, Digestive Diseases, and Kidney, which is where urologic research funding comes from. And so we, "we" meaning the faculty in the urology and urogynecology divisions, were participating in a clinical trial comparing Burch and sling procedures for stress incontinence.
Q And the slings that you were using were the cadaveric, the --
A Rectus fascia and what are called string slings, if you're familiar with that terminology.
Q And the string slings are what?
A I'm basically using sutures anchored in periurethral tissue.
Q Going back to my question trying to get an idea, I mean, granted that when you're talking about the vaginal surgeries and the colporrhaphy, for example, any of the other surgeries that you were doing, whether it's the colporrhaphy, the sacrospinal ligament fixation, all of those would involve vaginal surgery; correct?
A Correct.
Q And all of those would have involved a section of the vagina?
A Correct.
Q And I assume that you would say that as

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with colporrhaphy, any of the vaginal surgeries, whether it be the sacrospinal ligament fixation or others, would be more likely to be a combination procedure than a stand-alone, separate procedure?
A Yes.
Q Recognizing that, can you give me an approximation of, for example, the number of colporrhaphies that you performed, whether or not they were performed in conjunction with another surgery?
A I would estimate something in the neighborhood of 200 to 300 cases.
Q During the entire time that you were there?
A At Magee-Womens Hospital.
Q At Magee. And the same question with respect to the sacrospinal ligament fixation.
A Well, my preference was to perform the uterosacral ligament fixation, unless there was a special reason not to do that. So the sacrospinous ligament fixation would be less common for me to perform.
Q Divide the two, the uterine ligament fixation versus the sacral, and tell me approximately how many of each you would have done.

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A I would say probably 80 percent for the uterosacral ligament suspension and 20 percent for the sacrospinous ligament fixation.
Q And that 80 percent, what number would that be roughly equivalent to?
A Yeah, that's really difficult to answer. I could give you a guess as to the total number of surgeries. But as to the breakdown as to whether they needed an apical prolapse repair with an anterior and posterior -- and/or posterior vaginal repair...
Q Give me an approximation of the total.
A I think I did. Did I say 200 to 300?
Q Right. But I understood that was just colporrhaphy. You're suggesting that that's the --
A Oh, oh. Yes, yes.
Q That's the total?
A I meant that to be the total.
Q I'm sorry. I wasn't following. So that would basically include over that roughly three-year period at Magee you would have done 2 to 3 hundred surgeries total?
A For prolapse, correct.
Q Okay. And while you were there at Magee, were there any special textbooks or teaching

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protocols that you used in the fellowship?
A I mean, there are several textbooks that we used. Do you want me to try to list them?
Q Well, can you tell me what some of the textbooks were that were used with respect to the prolapse surgery?
A Well, for example, Mark Walters and Mickey Karram have a textbook on Urogynecologic and Reconstructive Surgery I believe is the title.
Q And were there others similar to that that were used or recommended in the course of the fellowship?
A There are some very classic gynecology textbooks like TeLinde's, atlases like Clifford Wheeless'. I have a textbook in office urogynecology. That's all I can think of at the moment. I'm sure there are many more.
Q I really was just trying to get a feel for the ones that you recollect might have been used or referred to in the course of that fellowship program there.
A Uh-huh.
Q So that represents the universe that you can remember at this moment; is that correct?
A Correct.

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Can we have another break?
MR. SLATER: Sure.
(Discussion off the record.)
(Luncheon recess taken from 12:41 p.m. to 1:52 p.m.)
BY MS. JONES:
Q Doctor, let me follow up with a couple of questions about some of your testimony this morning. You testified that most of the time when you did pelvic floor repair surgery that you used a combination of different techniques.
MR. SLATER: Objection.
You can answer.
THE WITNESS: No, I don't recall saying that. I used a combination of different procedures.
BY MS. JONES:
Q Fair enough. So that you would, for example, use colporrhaphy together with utero ligament suspension fixation, for example, or some other procedure?
A Uterosacral ligament suspension, yes, for apical prolapse if that was the patient's problem.
Q Why is it that you so often used a combination of two procedures?

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A It's the nature of the condition of prolapse.
Q Explain that to me.
A As surgeons we artificially segment the vagina into the apex, the anterior vagina, and the posterior vagina. In reality the vagina is a continuous tube. And when prolapse occurs, it's more likely to occur in more than one of the segments that we artificially designate than a single segment.
Q And because it occurs in more than one of those segments, it's necessary to do for optimal repair more than one procedure?
A Correct.
Q And in addition to those procedures, you would often also do a procedure for urinary incontinence at the same time, would you not?
A For stress incontinence.
Q Stress incontinence.
A Again, if that was the woman's problem, yes.
Q Understood. But stress incontinence often happens in conjunction with prolapse, does it not?
A Correct.
Q And when you would do an abdominal

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sacrocolpopexy, would you also do or use a combination of procedures?
A As necessary, yes.
Q So that, for example, even though you're doing an abdominal sacrocolpopexy, you might at the same time also be doing a vaginal surgery or colporrhaphy or some other procedure?
A Typically not a colporrhaphy. That wouldn't ordinarily be necessary to combine with an abdominal sacrocolpopexy.
Q What other procedures would you ordinarily combine with an abdominal sacrocolpopexy?
A A procedure for stress incontinence.
Q Now, I know that you told me that you used mesh when you were in Pittsburgh at the Magee-Womens Hospital in surgeries for abdominal sacrocolpopexy.
A Correct.
Q And you said in fairness that you did not remember what kind of mesh.
A Correct.
Q Can you describe for us the characteristics of that mesh that you used?
A No.
Q So you don't, for example, know whether it was a multifilament versus a monofilament?

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A I would prefer not to guess.
Q Fair to say you don't remember whether it was macroporous as opposed to microporous?
A Again, I would prefer not to guess.
Q And I assume that you don't know whether it was polypropylene versus Gore-Tex® versus Mersilene® or some other type of mesh?
A I would not have used Gore-Tex®. I am doubtful I would have used Mersilene®.
Q I think you told us that it was not partially absorbable?
A Correct. No, I didn't tell you that. That was in the context of the CARE trial.
Q Okay.
A That was part of the study design.
Q Do you know whether or not you have used a partially absorbable mesh?
A No, I did not.
Q But you don't know whether or not it was polypropylene?
A I cannot say that with certainty.
Q When you were performing a surgery using this mesh, did the mesh come, as you can recall, in a box, a separate piece of mesh?
A A flat rectangular piece of mesh, yes.

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Q And were there any instructions or anything else in the box that you remember looking at?
A Are you referring to the instructions for use?
Q Instructions for use or anything else that would have been within the box.
A I don't recall.
Q Did you modify or cut that mesh in any way?
A Yes.
Q While you were in the operating suite?
A At the scrub nurse's table, yes.
Q In other words, would you cut it after you had the patient, if you will, on the table in the course of the surgery after you had seen whatever the condition was?
A Yes.
Q You told us that you knew several people or had met several people in the context of professional meetings. What professional meetings prior to, you know, the end of 2006 did you normally attend?
A The American Urogynecologic Society meeting, the Society of Gynecologic Surgeons

meeting, and occasionally the meeting of the American College of Obstetricians and Gynecologists.
Q And do you continue to attend those meetings?
A No.
Q When is the last time you attended a meeting of any of those organizations?
A I believe that would be in 2008.
Q Did you, in fact, attend a meeting after you left the position as program director at the NIH?
A No, I don't believe so.
Q The reason I'm asking, according to your CV, you were there until 2007. So my question is once you left that group, have you attended any professional organizational meeting?
A No, I don't believe so.
Q And it would be a fair statement then that you've not personally presented at any meetings since that time?
A Correct.
Q Let me see if I can go back, a little further back. You were at the Cleveland Clinic from 1993 to 2000; correct?
A Correct. I had my fellowship in '92 to

'93.
Q That's what I want to go back to. As I appreciate your training, you went to college at the University of Maryland and finished there in 1983?
A Correct.
Q With a degree in microbiology?
A Correct.
Q Have you ever done any work in the field of microbiology since you finished?
A No, not since I graduated from college.
Q In other words, you've not been engaged in any laboratory or bench testing in any capacity with respect to the field of microbiology since you finished college?
A Correct.
Q Did you go directly from undergraduate to medical school?
A Yes.
Q And you finished medical school then in 1988?
A Correct.
Q And then you did a residency in OB-GYN?
A Correct.
Q And that was at Hartford?
A Hartford Hospital, yes.

Q And can you tell me when you were doing that residency from 1988 to 1992 -- it was a four-year residency?
A Yes.
Q -- during that time I assume you had various rotations?
A Correct.
Q In medical school itself, you would have had courses with respect to the anatomy; correct?
A Correct.
Q Those would have included courses in pelvic anatomy?
A Correct.
Q When you were doing your residency in OB-GYN, did you have additional training and courses in pelvic anatomy?
A Not a course per se, but it was certainly part of our curriculum.
Q That's a major part of the body that gynecologists deal with on a regular basis; correct?
A Correct.
Q And was it during the course of your residency then that you were taught how to examine patients for various conditions?
A Yes.

Q And I assume that during that residency you kind of covered a broad spectrum of gynecology --
A Yes.
Q -- and obstetrics?
So you would have delivered babies?
A During my residency, yes.
Q You would have provided routine gynecologic care to patients?
A Yes.
Q Counseled on contraception?
A Yes.
Q Counseled on or treated women for menopausal issues?
A Yes.
Q And would you also have performed surgery during that course of your residency?
A Yes.
Q In what areas?
A In obstetrics, in gynecology, in gynecologic oncology, and in the field of reproductive endocrinology and infertility, in which a lot of laparoscopic surgery is performed.
Q So when you say in obstetrics, that would be, for example, C-sections?

A Yes.
Q Did you perform any surgeries for stress incontinence?
A Yes.
Q At that point in time, this is 1988 to '92, what procedures did you use to treat stress incontinence?
A Primarily the Burch colposuspension.
Q And that was an open abdominal surgery?
A Preperitoneal, retropubic.
Q Any other procedures that were used to treat stress incontinence?
A Kelly plication.
Q Anything else?
A That's all I can remember.
Q Did you counsel with patients at that point in time about stress incontinence?
A Yes.
Q And offer them alternative treatments to surgery?
A Yes.
Q What alternatives did you discuss with the patients?
A Behavioral and lifestyle changes, fluid modification, avoidance of certain fluids or even

foods if that appeared to aggravate their problem, things like that, and pelvic muscle exercises and pessary use.
Q No question in your mind that stress incontinence can have an adverse effect on a woman's lifestyle?
A I agree with that.
Q And that it can affect her from a psychosocial perspective, if you will?
A It can.
Q That it can, you know, expose her to embarrassing circumstances that may lead some women to avoid participation in certain activities?
A It can.
Q It can certainly also affect a woman's sexual function?
A It can.
Q It is a condition that you as a urogynecologist certainly believes warrants treatment?
A Treatment is based on the patient's symptoms.
Q Understood. Treatment in the sense that women need to have various alternatives available, whether it's pelvic floor exercises or

pharmacological agents or surgery, to treat that condition?
A I'm not sure I understand your question. Could you rephrase that?
Q Let me see if I can put it in this perspective. Stress incontinence can pose a significant burden to a woman?
A It can.
Q You agree with that?
A Correct.
Q And the condition itself is serious enough that it's a condition that warrants the development of treatment for that condition?
MR. SLATER: Objection to the form.
You can answer.
THE WITNESS: Again, treatment is based on the patient's symptoms.
BY MS. JONES:
Q I understand. I'm not trying to suggest that every patient would receive the same treatment. I'm simply saying that the condition itself is serious enough and can pose, depending upon the patient, a significant burden such that different alternative treatments are and should be part of the physician's armamentarium to treat that condition?

MR. SLATER: Objection to the form.
You can answer.
THE WITNESS: Shall I explain what I'm struggling with?
BY MS. JONES:
Q That's fine.
A Okay.
Q Do that and we'll see if we can straighten it out.
A Okay. If we understood the etiology of stress incontinence, we could offer a specific etiology-based treatment. Right now our treatments are empiric, which means we don't fully understand the etiology so we're not able to treat the root cause. And in a perfect world we would understand the etiology fully, we would have an etiologic-based treatment, and we would be able to diagnose women with the specific cause of her incontinence. Incontinence is only a symptom, the end result of whatever abnormality has preceded it that allows that symptom to occur.
Does that help you or help --
Q Let me see if we can approach it this way: Incontinence is the result of a dysfunction in the pelvic floor system; correct?

A Not necessarily, not exclusively.
Q It can be?
A It can be.
Q We know that various conditions and events have been associated with stress incontinence; correct?
A Correct.
Q One of those is parity? I'm sorry. You have to say --
A Correct. I didn't realize that was the end of the question.
Q Well, I meant to have a question mark there. One of those would be not only parity, but it would include whether or not you'd had difficult vaginal deliveries of children; correct?
A It can.
Q Well, for example, one of the thoughts is that during the course of childbirth you can develop whether it's vaginal tears or damage to the muscle such that it may result in stress incontinence; correct?
A Well, that's exactly what we don't understand fully. Clearly there is an epidemiologic relationship between childbirth and the development of stress incontinence. To be able to say that this

specific injury in this specific woman led to the development of stress incontinence, that we are unable to say.
Q There are also other conditions that have been associated with stress incontinence; correct?
A Correct.
Q Obesity?
A Correct.
Q Certain medical conditions?
A Correct.
Q Such as diabetes, for example?
A Correct.
Q What are the other explanations that have been associated from an epidemiological standpoint with stress incontinence?
MR. SLATER: By the way, I just want to place an objection. Obviously I'm not going to tell her not to answer. And I understand the plaintiffs had an SUI in their past so it can be deemed relevant, but at some point I assume we're going to get to prolapse. Maybe.
THE WITNESS: Previous surgery for incontinence, being female.
BY MS. JONES:
Q How about age?

A Age does not have a direct relationship with the development of incontinence.
Q Anything else that you can think of that's been theorized to have a direct development relationship?
A Theorized?
Q That's fine. Answer the theorized.
A Menopause has been theorized, medication use, specific medications.
Q How about previous surgeries, hysterectomies?
A That's controversial. I wouldn't say that it's been established as an association.
Q In your practice you said that you, as I recall -- I'm not sure whether you said that you had prescribed this or whether it was available, so let me ask you. Did you prescribe pessaries for use for incontinence?
A Yes.
Q Did you prescribe pelvic floor exercises for incontinence?
A Yes.
Q That would be primarily the Kegel exercise?
A Kegel is, yes, the eponym attached.

Q I'm sorry?
A The eponym, the name of the doctor who described this in the literature.
Q Had you prescribed pharmacologic agents for treatment of stress incontinence?
A If I did, it would have been very rarely.
Q Very, very?
A Very rarely.
Q And obviously you have performed the Burch suspension?
A Correct.
Q Any other type of treatment that you either prescribe or surgical procedure that you perform for treatment of stress incontinence?
A The Kelly plication and sling procedures and injection of bulking agents, Durasphere®, for example, Contigen®. Those are the two names that I can think of at the moment.
Q When did you use Kelly's plication techniques?
A Typically in an elderly patient with mild to minimal symptoms where I felt their risks outweighed -- the risks of a different stress incontinence operation outweighed the benefits for the patient.

Q When I said "when," I was actually thinking in terms of time period.
A Oh.
Q Were you using that in your residency?
A Yes.
Q So you would have used it '88 to '92. Did you continue to use that throughout the time you were practicing?
A Yes.
Q When did you first begin to use the sling procedures?
A During my fellowship at the Cleveland Clinic.
Q That would have been 1992-93 then?
A Correct.
Q At that point in time what materials were you using for slings?
A Primarily rectus fascia.
Q And were there issues with recurrence with that surgery?
A "Issues" meaning?
Q Meaning that there were failures and that the condition recurred?
A Yes.
Q And do you know what that rate of

recurrence was?
A No.
Q I think you mentioned earlier today that at some point you used cadaveric tissues?
A I did not mention that. That had been used in -- at Magee-Womens Hospital. I did not use that material myself.
Q Why did you choose not to use that material?
A I didn't believe it was effective.
Q You didn't believe it was effective in the sense of providing long-term stability?
A Providing a long-term -- I don't like the word "stability," but a long-term solution for the patient's symptoms.
Q Were there also safety issues associated with cadaveric tissues?
A I don't believe that was to the extent of being clinically relevant. I think those were primarily theoretical.
Q The cadaveric tissues were used at Magee; is that correct?
A Correct.
Q Were they used at the Cleveland Clinic?
A I didn't use them. I don't recall if my

partners used them.
Q And am I correct that when you were in your residency, just the residency, '88 to '92, you were doing the Kelly's plication and the Burch procedure?
A And also the Marshall-Marchetti-Krantz, another retropubic suspension.
Q At the time that you were doing these surgeries, were there any published randomized controlled trials on any of these surgeries upon which you relied in terms of making your determination as to procedures to use?
A Not that I recall.
Q Let me see if I can turn to a little bit different subject now and talk with you about prolapse. When did you first perform any surgery for pelvic organ prolapse?
A That would be in the first year of my residency.
Q In 1988?
A Yes.
Q And can you tell me what procedure it was that you performed?
A In general that I performed during my residency?

Q Yeah. In all fairness, what I want to talk with you about is what you did for treatment of prolapse during your residency versus what you did during the fellowship. I just want to have an understanding of the differences.
A All right. So in my residency we were trained to perform the sacrospinous ligament fixation as the most common procedure used for apical prolapse. In my fellowship and during my residency, anterior and posterior colporrhaphy.
Q Can I stop you there and then come back to the fellowship? At the time that you were taught to do the sacrospinal ligament fixation for apical prolapse, it was a vaginal surgery; correct?
A Correct.
Q What were the risks associated with that surgery that you would discuss with the patient?
A There are the general risks of -- that apply across the board pretty much to surgery in general: Bleeding; infection; if bleeding was excessive, the possibility of a transfusion; the risks associated with anesthesia; the possibility of a blood clot.
Specific to this type of procedure: Recurrence of prolapse, voiding dysfunction, pain

with intercourse. And by "voiding dysfunction" I can expand on that if you like.
Q That's fine.
A Okay. So temporary inability to empty the bladder fully, urgency, frequency, urinary tract infection. So that's what I would consider -- not urinary tract infection specifically, but in speaking to the patient about urinary issues, that's what I would talk with her about.
Q Are there any other risks associated with sacrospinal ligament fixation that you can remember that you would talk with them about?
A Organ damage in general. We're working very close to the bladder, the rectum, nerves. Blood vessels goes in the category of bleeding.
Q What about potential nerve damage?
A Potential nerve damage, correct.
Q And when you indicated that you'd discuss the risks of painful intercourse, that's for I guess two or three different reasons: One, that that's a risk any time you're doing vaginal surgery; correct?
A Correct.
Q Two, there's a possibility that you could affect either the length of the vagina or the introitus in the course of the surgery?

A I -- that's a possibility.
Q And the third aspect with the sacrospinal ligament fixation specifically is that that surgery, if you will, often pulled the vagina to one side or the other so that it affected its anatomical structure; correct?
A That is correct in a temporary sense. That's the result of surgery. For example, if it were placed in the patient's right sacrospinous ligament, the axis of the apex would be deviated to the right temporarily. As healing occurred, the axis was -- became restored to its normal direction.
Q As I understand this, and I promise you I have very basic understanding of it, the vaginal wall was affixed by a suture to the sacrospinous ligament?
A Yes.
Q And that meant that it was attached generally on one side, the right or the left, depending upon what the condition was you were treating it for?
A Actually it depended on whether the surgeon was right- or left-handed typically. But, again, that was a temporary deviation that would resolve itself in the course of healing.

Q Were there any other risks that you would discuss with your patients when you were doing the sacrospinous ligament fixation?
A I can't think of any others on the top of my head.
Q Now, I stopped you because you were getting ready to say that that's what you did in your residency prior to 1992. And then that somehow changed or evolved when you began your fellowship or did your fellowship?
A Correct.
Q How did that evolve?
A In the group of surgeons they were performing a range of surgeries: Sacrospinous ligament fixation, uterosacral ligament suspension, iliococcygeus muscle suspension. Those were the three vaginal apical procedures.
Q And I think you told us that you at least came to prefer the uterine --
A Uterosacral ligament suspension.
Q And why was that?
A I felt it provided good restoration of the -- good correction of the vaginal prolapse and it was relatively easy to teach to residents and fellows.

Q Was it an easier surgery to perform than a sacrospinal ligament fixation?
A I don't know if I would qualify it as easier. It required less dissection in the very deep pelvis in the region of the sacrospinous ligaments, obviously. If we're not doing a sacrospinous ligament fixation or a Prolift® procedure, we're not needing to dissect around the sacrospinous ligaments.
Q And how would your discussions with the patients about the risk of the uterine sacrospinal suspension differ from what you discussed with patients with the sacrospinal fixation, ligament fixation?
A Uterosacral ligament suspension carries a slightly higher risk of ureteral injury because of where the stitches are placed. During surgery a cystoscopy is performed to check whether the ureters are still patent after the stitches have been tied down. And if they're not, one or the other, then we address that immediately and the patient doesn't have any additional morbidity from that point. But I would alert the patients that that was a possibility and we would not leave the operating room until we were sure that that was not the case.

Q Other than that, the other risks remain the same?
A Similar.
Q Well, you essentially have the same potential complications associated with the surgery in terms of the anesthesia complications, the bleeding complications, perforation complications? All of those things would have remained the same?
A Yes.
Q It was also a vaginal surgery so there would also be the risk of painful intercourse?
A Yes.
Q During the time that you were practicing medicine or surgery, throughout that period of time did you continue to perform and treat the uterine sacral ligament suspension procedure for treatment of the apical prolapse?
A Yes. I would prefer to perform the uterosacral ligament suspension unless I felt that wasn't the best procedure for the patient.
Q And did you continue under other occasions to use the sacrospinal ligament fixation?
A The sacrospinous ligament fixation, yes.
Q I'm sorry. You mentioned the issues with possible urethral damage in the course of the

surgery.
A Excuse me. Ureteral.
Q Ureteral. Was voiding dysfunction also a potential complication of the uterine sacral ligament fixation?
A Uterosacral ligament fixation, yes.
Q I'm going to get these terms right one of these days.
MR. SLATER: It's all right. Your opening's two months away.
MS. JONES: I'm sorry?
MR. SLATER: I said it's all right. Your opening's two months away. You have plenty of time.
MS. JONES: I won't be able to pronounce them then.
MR. SLATER: Two months from Wednesday.
BY MS. JONES:
Q Can you have ongoing voiding dysfunction associated with sacrospinal ligament fixation?
A That has not been my clinical experience.
Q Have you seen that reported in the medical literature?
A No.

Q Have you seen it reported in the medical literature associated with the uterosacral ligament fixation?
A Maybe I can back up and you can make sure we're talking in the same way. You described voiding dysfunction that was -- can you say it again?
Q I said ongoing.
A Ongoing.
Q It continues after just the immediate surgery.
A Okay. So for how long?
Q For any length of time.
MR. SLATER: Objection.
You can answer.
THE WITNESS: In my experience the voiding dysfunction that occurs after uterosacral ligament suspension or sacrospinous ligament fixation is in the range of days, occasionally weeks.
BY MS. JONES:
Q Have you seen reported in the literature voiding dysfunction that lasts longer than that?
A Longer than what?
Q Well, you just said that you generally saw

it last days and sometimes weeks. I'm asking about being reported that it's a longer lasting and perhaps permanent condition.
A I don't believe I've ever seen it recorded as a permanent condition.
Q Have you ever seen it being reported as longer lasting requiring subsequent treatment?
A Not after an apical suspension. That typically -- if that occurs, it's because an anti-incontinence operation was performed at the same time that requires treatment.
Q While you were in your residency, do you have any idea how many sacrospinal ligament fixations you performed?
A No.
Q Was it common in your residency for you to perform pelvic floor repair surgery? In your residency.
A What do you mean by "common"?
Q Well, how many pelvic floor repair surgeries did you do during your residency?
A I don't know.
Q Other than the sacrospinal ligament fixation, what other surgeries did you perform?
A Specific --

Q During your residency.
A Specific to prolapse?
Q Prolapse, yes.
A Uterosacral ligament suspension. I don't believe that included abdominal sacrocolpopexy. And it would include anterior and posterior colporrhaphy.
Q Do I understand that you do not have a recollection of doing the abdominal sacrocolpopexy during your residency?
A Correct.
Q But you did do anterior and posterior colporrhaphies?
A Correct.
Q Tell me what you understood the potential complications and risks associated with anterior/posterior colporrhaphies to be.
A They would be very similar to the risks of the uterosacral ligament suspension and the sacrospinous ligament fixation.
Q Any major differences that you can recall in terms of what you would have discussed with your patients?
A No, I don't think so.
Q Any other surgeries that you would have

performed during your residency for prolapse?
A For prolapse? No, I don't think so.
Q Then let's go into your fellowship. You did your fellowship at the Cleveland Clinic. And this was a one-year fellowship; am I correct?
A Correct.
Q Other than just the length of it, how did that fellowship differ from the fellowship at Magee that you were involved with later on?
A At Magee we were particularly interested in training academicians. And in order to provide them with the background to design and perform high-quality research in their careers, they obtained a Master's degree, a Master's of Science degree in clinical research as part of their second year of fellowship. I did not have that opportunity in my fellowship so that was something I did a little later.
Q Anything else in terms of the actual surgeries or patient care that you performed?
A The setup of my fellowship was divided amongst the three divisions in our department of gynecology. So there was a four-month block in the division of benign gynecology, which was primarily vaginal surgeons doing reconstructive surgery; a

four-month block with the gynecologic oncologists, working with them in their care of patients with gynecologic cancers; and a four-month block with the division of reproductive endocrinology and infertility, which, as I said before, is primarily laparoscopic surgery.
Q So of that year of fellowship that you did, if I'm correct, you had a four-month block in which you concentrated on pelvic floor reconstructive surgery that would have included whether it's prolapse or stress incontinence surgeries?
A Correct.
Q And other than the fact that you began using the uterosacral ligament procedure for apical reconstruction, was there any other differences in the surgeries that you performed --
MR. SLATER: Objection to the form. You can answer.
BY MS. JONES:
Q -- as a fellow as opposed to a resident?
A I believe what I said is that uterosacral ligament suspension was performed during my residency, not as commonly as the sacrospinous ligament fixation. I didn't experience training in

abdominal sacrocolpopexy until I reached my fellowship.
Q I apologize. When you got the training for the abdominal sacrocolpopexy, at the time was mesh used in that procedure?
A Yes.
Q And can you tell me what kind of mesh was used in that procedure?
A No.
Q Do you know whether it was multifilament or monofilament?
A No.
Q Do you know whether it was polyethylene as opposed to Mersilene® or Gore-Tex® or something else?
A It wasn't Gore-Tex®, but I don't know what it was.
Q Did you use mesh in all of your abdominal sacrocolpopexies?
A Yes.
Q And was that true throughout the time that you were performing surgeries?
A Yes.
Q When you would counsel a patient about abdominal sacrocolpopexy, how would you counsel them

about the risks of that surgery?
A So all of the other risks that we've already discussed and, in addition to that, the risks specific to mesh, mesh erosion, mesh infection, the possibility of repeat surgery, if a mesh complication occurred in which the mesh needed to be removed, and then the risks associated with laparotomy, so bowel adhesions, small bowel obstruction, the need for a reoperation if that occurred, sometimes, not always, scarring, of course, you know, an abdominal scar. I think that's everything I can think of at the moment.
Q Was there anybody specifically who trained you on abdominal sacrocolpopexy?
A Mark Walters.
Q Is that the Mark Walters who's associated with the International Academy of Pelvic Surgery?
A Yes.
Q And was he your principal mentor during your fellowship?
A I don't know that I would describe him as a mentor. He joined the staff as I -- no. Actually he joined the staff in August of 1993 just after I had finished my fellowship and joined the staff. And since I hadn't -- oh, I guess I misspoke then

because I've been describing the abdominal sacrocolpopexy as if it occurred in my fellowship. But, no, he joined the year -- the month after I finished my fellowship. So that would have actually occurred in the following year. So I misspoke about that. Because the surgeons who were already there did not perform abdominal sacrocolpopexy. I would describe him as a colleague.
Q Was it Dr. Walters that introduced the use of abdominal sacrocolpopexy at the Cleveland Clinic then?
A Yes.
Q Prior to doing your first abdominal sacrocolpopexy, had you done any surgery using mesh?
A The only possibility I can think of, and I'm not certain of this, but it would be with the oncologic surgeons if they had an abdominal reconstruction from a hernia or some other postoperative event; otherwise, the answer would be no.
Q You yourself don't have any recollection of doing any hernia repair surgery, do you, or do you?
A Not by myself. It would be oncologists.
Q I understand. My question is did you

perform hernia repair surgery going through your oncology training?
A In the four-month block with the oncologists, I do recall performing hernia repairs with them, yes.
Q And do you remember whether or not mesh was used?
A It's a possibility. I cannot recall that with certainty.
Q You think your first abdominal sacrocolpopexy would have been in 1993?
A Correct.
Q At that time did you know whether any mesh had been cleared by the FDA for use in abdominal sacrocolpopexy?
A No. To my knowledge, Gynemesh® PS mesh was the first to be cleared by the FDA for an indication in pelvic reconstructive surgery. That was in 2002.
Q Do you know, Doctor, whether or not the mesh that you used in 1993 had been cleared by the FDA for any use?
A I would assume so.
Q Do you know what use it was cleared for?
A Since I don't remember the specific mesh,

I don't think you want me to guess.
Q Do you know of any mesh cleared for use in prolapse or stress incontinence surgery before 1996?
A I am not specifically aware of the dates revolving around the FDA clearance of stress incontinence products.
Q You're not aware of any mesh being cleared for use in pelvic reconstructive surgery before Gynemesh® PS?
MR. SLATER: Objection.
THE WITNESS: Correct, that is my understanding.
BY MS. JONES:
Q The use of mesh in abdominal sacrocolpopexy was a use that was developed by physicians; correct?
A I would assume so.
Q Historically there had been abdominal sacrocolpopexy performed without using mesh, had there not?
A Correct.
Q And there had been some problems with the use of other tissues like the autologous tissues or other graft tissues associated with it; correct?
A Problems?

Q Problems with recurrence?
A Yes.
Q And one of the reasons that the doctors resorted to the use of mesh was to provide a better anatomical repair with less recurrences; is that correct?
A What do you mean by a "better anatomical repair"?
Q Well, you tell me why you used mesh in abdominal sacrocolpopexy.
A Because it was the best alternative at the time.
Q And why was it the best alternative at the time?
A Because typically the vagina isn't long enough to reach the sacrum by itself, so you need a bridging material. And use of materials such as -- autologous materials required harvest of a large amount of natural tissue from the patient, so that's a downside. And then other materials, Unigraft materials, had issues with increased recurrence of prolapse.
Q There obviously was some morbidity involved with patients from the stripping of the fascia in preparing the autologous tissue; correct?

A Correct.
Q Forgive me, Doctor, I think I asked this question, but I can't remember. In terms of discussions of the complications with the patients, and you're talking about the abdominal sacrocolpopexy, the complications that you would discuss were essentially the same as with the other surgeries that we've already discussed plus the ones involving mesh that you described; correct?
A Correct; and the risks specific to the abdominal approach.
Q The risks specific to the abdominal approach in addition to the scarring and so forth, it's an open surgery that takes longer to heal, for example, and generally it's a longer surgery than some of the others, is it not?
A No, I don't agree with that.
Q You do agree that it generally takes patients longer to recover from the abdominal sacrocolpopexy than from a vaginal surgery?
A Well, can you be more specific about what you mean by recovery? Do you mean return to work? What do you mean?
Q Well, if you were to counsel a patient on abdominal sacrocolpopexy and you were going to tell

them how long it was before they would return to their normal lifestyle, whether it's work, activities, whatever, how would you counsel them?
MR. SLATER: Objection; vague.
You can answer.
THE WITNESS: I would counsel her that she should expect to be off work in the neighborhood of six to eight weeks.
BY MS. JONES:
Q And what would you tell her about how long it would be before she could drive?
A Drive? That's variable. I would recommend to patients they not be taking pain medication -- they should get to the point in their recovery when they are no longer in need of taking pain medication before they begin driving.
Q And how long would it be that you would tell someone that they would need to avoid exercise, for example?
A Six to eight weeks and once I had checked them twice usually in the office before releasing them to that kind of activity.
Q And how long should they avoid intercourse?
A Similar range, six to eight weeks and

until I had seen them.
Q If you were in contrast advising a patient who was having a colporrhaphy, how long would you tell her it would take her to recover?
MR. SLATER: Objection.
You can answer.
THE WITNESS: Six to eight weeks.
BY MS. JONES:
Q And would you tell her on all of the other issues exactly the same as you would say on the abdominal sacrocolpopexy?
A Correct.
Q How long would you tell her she'd be in the hospital?
A Usually two days.
Q How long was somebody in the hospital with abdominal sacrocolpopexy?
A Usually two days.
Q At the time that you started using mesh in the abdominal sacrocolpopexy, were there any randomized clinical controlled trials regarding the use of mesh in that surgery?
A Compared to what?
Q Compared to using it without. Were there any randomized controlled clinical trials of which

you were aware of involving abdominal sacrocolpopexy when you started using mesh in 1993?
A No.
Q Am I correct, Doctor, if you know, that mesh had actually been used in abdominal sacrocolpopexy by surgeons since the 1970s?
A No, I don't know when abdominal sacrocolpopexy with mesh began to be used.
Is this a good time for a break?
MS. JONES: Okay.
MR. SLATER: Sure.
(Short recess.)
BY MS. JONES:
Q Doctor, are you currently licensed to practice medicine?
A No.
Q Do you know when you were last licensed? Would it have been 2006?
A No. I believe I carried my license through to the end of 2007.
Q Have you attended any continuing medical education courses since that point in time?
A No.
Q Are you Board-certified in any specialty?
A No. I was Board-certified in obstetrics

and gynecology and I did not maintain that when I discontinued my clinical practice.
Q And were you ever Board-certified in any subspecialty of urogynecology?
A No. At that time the Board had not yet created subspeciality certification for individuals. They were only certifying fellowship programs.
Q When you were at the Cleveland Clinic after you finished your fellowship, you stayed on, can you describe for me what you did at the Cleveland Clinic for that period from '93 to 2000?
A Yes. My clinical practice started as a general gynecology practice. When I realized I needed a stronger background in clinical research design and performance, I attended the program at the University of Michigan and obtained a Master's of Science degree in clinical research design and statistical analysis.
And when I completed that, my chairman created a new position of director of clinical research in the department and appointed me as the first in that position. And in that role I advised the other faculty members and fellows and residents in designing and performing their own research. I performed my research in conjunction with my

colleagues in our division and our fellows and residents. And then in 1999 I began working with the NIH.
Q Well, let me see if I can break this down a little bit. When you took the Master's of Science degree, did you take a leave of absence to go and get that degree?
A No.
Q Did you attain that by a correspondence school? How did you obtain that degree?
A University of Michigan has a special arrangement. They call it on job/on campus for people who travel in -- they have local people, too, but who can travel in from other states where the classes are held from Thursday to Sunday one day a month -- excuse me -- once a month. And in that way the Master's is completed with its full credits in just under two years.
Q All right. So from '97 then to '99 you were spending four days a month working on your Master's at -- was that at Ann Arbor?
A Yes.
Q And you said your practice was a general gynecology practice?
A Yes.

Q So that you were seeing women and were you also doing obstetrics?
A No.
Q Were you seeing women then in an office setting where you were counseling them on contraceptive, menopause, doing your annual checkups and so forth?
A Correct.
Q And was that the case, did you follow that practice throughout your tenure at the Cleveland Clinic?
A No.
Q When and how did that change?
A Within a couple of years, with the support of my chairman, he recognized my special interest in pelvic floor disorders and we arranged that my clinical practice would focus on that to the exclusion of other general gynecology issues and regular well women care.
Q And who were the other members of the staff at the Cleveland Clinic who focused on pelvic floor issues?
A Mark Walters; Lester Ballard, B-A-L-L-A-R-D; Delbert Booher, B-O-O-H-E-R.
Q And when you began, it would have been

sometime then around 1995-96 that you began to move into the urogynecology practice?
A Urogynecology had always been a portion of my practice. It was at that time that it became exclusive -- my practice was exclusive to urogynecology.
Q At that point in time then is it fair to say while you were at the Cleveland Clinic that you had done colporrhaphies?
A Yes.
Q Sacrospinal ligament fixation?
A Sacrospinous ligament fixation, yes.
Q The uterosacral ligament suspension?
A Yes.
Q The abdominal sacrocolpopexy?
A Yes.
Q Various sling or Burch procedures for stress incontinence?
A Yes.
Q Anything else?
A The Kelly plication and paravaginal repair.
Q While you were at the Cleveland Clinic, do you have any idea how many prolapse surgeries you performed?

A I would estimate in the range of 1,500 to 2,000.
Q Between '93 and 2000?
A Yes.
Q And what type of procedure did you perform the greatest number of?
A For apical prolapse, it would be the uterosacral ligament suspension. For anterior and posterior vaginal prolapse, it would be anterior and posterior colporrhaphy.
Q I didn't ask the question very well obviously. I'm trying to figure out in terms of your patient population, did you treat patients more for apical prolapse or for anterior and posterior prolapse?
A I really can't tell you that.
Q Do I recollect correctly that you said that you did surgery one day a week at the Cleveland Clinic?
A Typically, yes.
Q On your CV you say that you were also involved in the education of medical students in core rotation obstetrics and gynecology while you were there?
A Yes.

Q What did that consist of?
A A four- to six-week rotation where the medical students -- actually obstetrics and gynecology was four to six weeks. So the gynecology portion would be roughly half of that. And they would attend office with us, they would come to surgery with us, see postoperative patients in the hospital, attend lectures, and so on.
Q Were you involved prior to obtaining your Master's in research?
A Yes.
Q What percentage of your time was spent in research?
A I think at that time I had a half day that was not otherwise in the office or in the OR, in the operating room.
Q And that half day would have been when you did whatever research you were engaged in?
A And what would otherwise be called spare time.
Q Did you have any administrative responsibilities?
A Not at that time.
Q In 1999 when you took the position as program director for the pelvic floor disorder

program, at that point in time when you were at the Cleveland Clinic you were spending 25 percent of your time I think doing that is what you testified; correct?
A Yes.
Q And that would have been further from '99 until 2001 when you left the Cleveland Clinic?
A Yes.
Q And why did you leave the Cleveland Clinic?
A There was an opportunity at the University of Pittsburgh. As I mentioned earlier, the chairman very much wanted to develop a fellowship program and the faculty who were there didn't really have the skill set or the experience to make that happen.
Q At any time while you were practicing medicine, Doctor, did you have your privileges suspended?
A No.
Q Did you ever have your license restricted in any way?
A No.
Q Other than the one lawsuit that we talked about earlier, have any other claims filed against you?

A No.
Q If I look at your CV, there's a reference to 2001 a Presidential SGS Member Prize Award. What was that?
A Could you just remind me where you are?
Q It's on Page 3.
A Oh, yes. So that was a research award for a presentation. I believe the 2000 one was the anterior colporrhaphy trial. And the one in 2001, I can match it to my abstract if you want me to. I don't remember off the top of my head what that was for. Okay. So the anterior colporrhaphy trial was I was awarded -- myself and my co-authors were awarded that first prize, Presidential SGS Member Prize in 2001. And then in 2000 myself and Dr. Walters were awarded the 1st Prize Presidential SGS Member Prize for our study about the cost-effectiveness of urodynamic testing.
Q While you're looking at that, first of all, both of those prizes would have been joint awards to whoever the authors were on those papers?
A Yes.
Q And then the next one is Best Poster Presentation. Tell me what that topic was in 1999.
A Okay.

MR. SLATER: Best poster? I remember that. First grade. I always made the best poster.
THE WITNESS: Science fair my sister said.
Okay. That was for our study on sexual function in women before and after surgery for pelvic organ prolapse and urinary incontinence.
BY MS. JONES:
Q And then you have the ACOG/Ethicon Research Award for Innovations in Gynecologic Surgery in 1996?
A Yes. That was for the research proposal that turned out to be the anterior colporrhaphy trial.
Q And was that awarded to you as well as the folks that were the co-authors of the --
A The institution, to the Cleveland Clinic.
Q And then if you look down here, the Prize Paper, American Urogynecologic Society, in 1996, what was that?
A I believe that was the "Sexual function and vaginal anatomy in women treated with sacrospinous ligament suspension and pelvic reconstruction."
Q If we look under "Professional Service,"

you have that you were a member of the editorial board of Obstetrics & Gynecology. Obstetrics & Gynecology is the publication of ACOG?
A Yes.
Q And that publication of ACOG would go to all of the members of the American College of Obstetrics and Gynecology?
A Yes.
Q That is a peer-reviewed journal?
A Yes.
Q Can you tell me how you as an editor on that journal were involved in the peer review?
A Yes. As a member of the editorial board, we have a greater role in the review of manuscripts. A manuscript is typically sent out to two or three reviewers. One reviewer will be a member of the editorial board and the other one or two reviewers will be a member of the OB-GYN community. And we also participated in the editorial board meetings where we discussed matters of editorial policy, et cetera.
Q Let me ask this question: If somebody is a researcher and they complete a study, they submit a paper for publication, does that paper automatically go out to peer reviewers?

A It does at the Journal of Obstetrics & Gynecology, yes.
Q So it automatically goes out to peer reviewers and then those peer reviewers, are those peer reviewers chosen as ideally people that are, quote, expert in the field of the subject matter of the paper?
A I think it depends. When there are two or three reviewers, I think the editor would decide to send the manuscript to one or two people who are expert in the field and perhaps an additional reviewer who's not necessarily an expert to make sure that it's explained well enough to someone who's not an expert.
Q And the purpose of that peer review, though, is more than just looking at it from the standpoint of whether or not it reads well?
A Yes.
Q Its purpose is also to ensure as best they can the validity of the scientific methods and conclusions that are described in the paper?
A I would describe it as a process of evaluation of the scientific methods, data analysis, presentation, conclusions drawn.
Q And following that peer review, those peer

reviewers will send their comments back to the editorial board or do they go directly to the author of the paper?

A No. To the editor. There's an editor and then there are associate editors in the broad specialty areas of obstetrics and gynecology. So the reviewers' comments will go back to the appropriate associate editor. And the main editor could be involved, if necessary, deciding what the disposition of the paper would be, whether it would be rejected, rejected with possibility of rereview if it were resubmitted, or acceptance.

Q So once it goes out to the peer reviewers, it's returned to the editor and at that point in time the editor can either reject it or can send it back to the authors to make corrections?

A To receive the feedback from the reviewers and make changes as the authors decide.

Q And then it would be resubmitted to the editorial board and is it sent back to the peer reviewers?

A Typically.

Q And then it's sent back to the editorial board that makes the final decision on acceptance or publication?

A Yes, acceptance or rejection.

Q And so before it is ultimately accepted for publication, assuming there have been any changes to be made, it's been sent out to the peer reviewers at least twice?

A Typically, yes.

Q And that process applies to original research that's submitted?

A Yes.

Q Does it apply to review articles that are submitted?

A Yes.

Q Does it apply to letters to the editor?

A No.

Q Other than on Obstetrics & Gynecology, have you served on the editorial board of any other peer-reviewed journal?

A Not on the editorial board, no. I've been a peer reviewer -- I think that's on the next page -- yes, of several other journals.

Q And when you say you were a peer reviewer, they may just periodically call you and ask you to look at some paper that's been submitted?

A Correct.

Q And are you compensated for that?

A No.

Q On your CV it says that you were a peer reviewer on all of these at present?

A Correct.

Q Can you tell me when the last time you peer-reviewed an article for Obstetrics & Gynecology was?

A I would estimate perhaps a year ago.

Q That would have been 2011?

A Yes.

Q Do you remember whether or not the article that you peer-reviewed was published?

A No, I don't.

Q What about the American Journal of Obstetrics and Gynecology; when's the last time you peer-reviewed something there?

A That might be a little longer, perhaps 2010. I don't remember exactly.

Q What about the American Journal of Gastroenterology?

A That would be less. That would even be a little farther away, maybe 2008.

Q How about the British Journal of Obstetrics and Gynaecology?

A I don't remember exactly. A couple of

years I would guess.

Q How about the Cleveland Clinic Journal of Medicine?

A Again, I would guess a couple of years.

Q How about Diseases of the Colon & Rectum?

A A couple of years.

Q How about Evidence-based Obstetrics & Gynecology?

A Probably a couple of years.

Q Gastroenterology?

A Probably a couple of years.

Q International Urogynecology Journal?

A That might be more recent, perhaps a year or two ago. I'm not sure.

Q How about the Journal of Pelvic Surgery?

A Probably a couple of years ago.

Q How about the Journal of Reproductive Medicine?

A Probably a couple of years ago.

Q How about the Journal of Urology?

A Probably a couple of years ago.

Q How about the Journal of Women's Health?

A Probably a couple of years ago.

Q How about the Medical Science Monitor?

A Probably a couple of years ago.

Q How about the Neurourology and Urodynamics?
A Probably a couple of years ago.
Q Fair to say you have not peer-reviewed any journal article in 2012?
A Correct.
Q If I remember your testimony, you're not sure that you peer reviewed anything in 2011?
A Correct.
Q The last time you remember peer-reviewing anything would have been 2010?
A I'm not sure.
Q Could it have been longer ago than that?
A It could have been.
Q Other than in the case of abdominal sacrocolpopexy, have you ever taught a resident or fellow about the use of mesh in pelvic floor repair surgery?
A Well, as I said, at or around the time I was leaving the Cleveland Clinic, we were beginning to use the TVT®. So in that setting, yes.
Q And I think you told us you did not use the TVT® in Pittsburgh?
A Correct; except -- no. Excuse me. Never mind.

Q Have you used TVT® to correct stress incontinence at any time after you left the Cleveland Clinic?
A No.
Q On how many occasions did you use it at the Cleveland Clinic?
A I can give you a range of perhaps 10 to 20.
Q And that would have been shortly before you left?
A Correct.
Q And am I correct that you never used other mesh slings other than the TVT®?
A Correct.
Q And did you use only the TVT® or did you use the TVT® Obturator?
A No, not the TVT® Obturator.
Q And was there a reason that you did not use the TVT® once you moved to Pittsburgh?
A The experience at Pittsburgh, at the University of Pittsburgh Magee-Womens Hospital, was in using slings of rectus fascia. And I agreed with that practice and that's how I performed slings.
Q So at the time that you joined the staff at Magee, they were using the autologous tissue and

had not used mesh at all; correct?
A I don't know that.
Q What I'm trying to ask, was there anything about your experience with the TVT® that caused you to abandon the use of the TVT® or was it that you went to Magee and they were using the autologous tissue and you just adopted that?
A I think it's always preferable to perform a surgery without mesh.
Q Prior to that point in time, had you had any adverse experiences with the TVT® surgery that led you to abandon it?
A Not with my patients, not in patients who I personally operated on, but as a referral center we are referred patients who have complicated problems. So I have removed TVT® slings for mesh complications.
Q Did you do that in the Cleveland Clinic?
A Yes.
Q Did you do that at Pittsburgh?
A No. The community was not using mesh to the degree that was occurring in Cleveland, I believe. So I don't recall personally seeing referrals for mesh complications.
Q You told us that when you began using mesh

for abdominal sacrocolpopexy, that you would discuss with your patients the complications potentially associated with mesh?
A Yes.
Q And that would be including mesh exposure or erosion?
A Yes.
Q Mesh contraction?
A Yes.
Q I think you mentioned the possibility of infection?
A Infection, yes.
Q Anything else that you would counsel your patients on?
A The possibility of a fistula development, enterovaginal or rectovaginal.
Q And was that true, I mean your counseling of your patients about that group of potential complications remained true from 1993 throughout your practice?
A Yes.
Q While you were practicing, did you maintain any database or registry of the patients on whom you performed surgeries?
A No, not unless they were involved in one

of our specific research protocols.
Q I know. I was trying to separate that out and ask whether or not you kept a personal list or file of surgeries that you performed and so forth.
A No.
Q We have been talking about prolapse. Would you consider prolapse to be a pelvic floor disorder?
A Yes.
Q And would you consider prolapse to be a pelvic floor disorder that can pose serious problems for women?
A It can.
Q As we talked about with incontinence, it can also affect a woman's lifestyle or confidence?
A It can.
Q Can be an embarrassing situation?
A Are you comparing incontinence and prolapse or just restricting --
Q No, not at all. I'm just asking in general. I was really referring back to what we had talked about earlier only, not necessarily comparing the two.
A Okay. Yes. Then the answer is yes.
Q The answer is, yes, that it can be

embarrassing. Can it affect either the ability or desire for sexual relations?
A What do you mean by "ability"?
Q Well, can it affect sexual function?
A It can affect sexual function.
Q Can it affect sexual satisfaction?
A It can.
Q Can prolapse impair bowel movements depending on the type of prolapse?
A It can.
Q Can it affect urinary incontinence?
A Can you specify that?
Q Well, can it affect either urinary incontinence or urinary retention?
A I don't know that it affects urinary incontinence. Urinary retention can be associated with very advanced prolapse.
Q In terms of the symptoms that a woman often reports, she might report a feeling of pelvic heaviness or a bulge from time to time?
A Yes.
Q Have there been or are there risk factors associated with prolapse?
A I don't think I understand your question.
Q What factors have been identified as

potential causes of prolapse?
A Okay. Again, we talked earlier about not completely understanding the etiology of stress incontinence. The same thing applies to understanding the etiology of prolapse. My understanding of the development of prolapse begins with some element of pelvic muscle dysfunction that leads to undue strain on the connective tissue attachments to the vagina they were not by nature designed to withstand, and so over time those connective tissue attachments can stretch or possibly break resulting in loss of support to the vagina. And since the other organs in the pelvis -- the bladder, the uterus, the rectum -- rely primarily on the vagina for support, when the vagina loses support, the pelvic organs prolapse.
Q You said that it was your understanding that it was a disorder of the muscles in the pelvic floor?
A A dysfunction of the pelvic muscles.
Q And the dysfunction of the pelvic muscles can be painful?
A Not the type that leads to prolapse. In the way I'm speaking of dysfunction at this moment, it's a weakness or a laxity, a loss of tone or

strength, not a painful condition.
Q Let me just ask the question and understand that. Has pelvic muscle dysfunction been associated with pelvic pain?
A "Dysfunction" is a very broad term. I prefer to speak specifically of what I believe is affecting the pelvic muscles. Are they hypertonic? Is that a reason for pain? To my understanding, laxity associated with prolapse does not cause pelvic muscle pain.
Q Are other forms of pelvic muscle disorder, whether it's dystonia or something else, associated with pelvic pain?
A Yes. Hypertonicity, spasm, myalgia, a number of terms that, yes, are associated with pain.
Q And those disorders that are associated with pelvic pain are disorders that are seen and treated by gynecologists and urogynecologists?
A Yes.
Q Now, if we're looking at the factors associated with prolapse, they may be genetic factors, for example?
A Possibly.
Q So, for example, family histories have been associated with prolapse?

A Yes.
Q There's some thought that connective tissue diseases or other diseases might be associated with prolapse?
A Might be.
Q Obesity has been associated with prolapse?
A Yes.
Q Childbirth has been associated with prolapse?
A Yes.
Q Have conditions that are stress or strain on the musculature, for example, constipation, been associated with prolapse?
A To my understanding, that is more theoretical than evidence-based. I think it's plausible, but I don't think it's well supported by the literature.
Q How about age being associated with prolapse?
A Age, yes.
Q Menopause?
A Menopause, again, theoretical but not well supported.
Q How about smoking?
A Theoretical, not -- I don't believe I've

seen literature supporting an association between smoking. Chronic coughing is often listed. And, again, that's something that's more anecdotal and not, to my knowledge, well supported in the literature.
Q Chronic coughing has been associated much like constipation has in the sense of it putting stress or strain on the pelvic musculature?
A Correct.
Q Are there other identified factors that have been associated with prolapse?
A Lifting, heavy physical work, that falls into the category of the constipation and the chronic coughing. Again, really anecdotal.
Q How about exercise?
A Yeah, that's a confounder. Obviously a very general term. So there may be some exercises that are actually beneficial in terms of protecting or strengthening the pelvic floor and preventing or ameliorating prolapse and then there may be exercises that are -- have a relation with increased intra-abdominal pressure and have that theoretical association with prolapse.
Q If a patient came to you with prolapse, and just for our purposes right now let's say just a

general prolapse, you can pick any kind you want, I assume that you would agree with me, and I think this is what you've said, that any consultation and treatment has to be geared specifically to the patient's condition?
A To the patient's symptoms.
Q Patient's symptoms.
A Yes.
Q And as a surgeon when you're advising a patient or consulting with them on the alternatives for treatment of those symptoms or conditions, it's important to discuss the broad range of those possible alternative treatments?
A Yes.
Q And in discussing those treatments with a patient, depending upon her condition, among the alternative treatments that would be considered would be, one, doing nothing and just observing the condition for a while to see how it developed; correct?
A Correct.
Q Two, suggesting the use of certain pelvic floor muscle exercises --
A Correct.
Q -- to strengthen the muscles; correct?

A Correct.
Q Three might be the use of pessaries?
A Correct.
Q And four might be the use of different surgeries; correct?
A Correct. I would also add behavioral and lifestyle changes.
Q And when you say "behavioral and lifestyle changes," tell me what changes you would include within that.
A I would inquire as to her bowel habit and ask her about things like straining; and if that's a problem for her, to address that. Almost regardless of whatever other form of treatment she chooses, if any, I would want her to stop doing that, straining.
Q And so to accomplish that would you prescribe, for example, a laxative or some other pharmacologic agent or how would you change that? Change her eating habits?
A Well, pharmacology would be one way to go. Eating habits. You have to learn what the patient's already doing obviously to be able to suggest what will work for her, what she's going to be willing to accept and so forth.
Q And as a surgeon when you counsel a

patient about the different surgical alternatives, one of the issues that would be important would be for the surgeon to counsel with respect to procedures with which he or she is comfortable and familiar; correct?

A Correct.

Q And if he or she is not comfortable or familiar with doing a particular surgery that the patient needs, then it would be appropriate to refer that patient elsewhere?

A I agree with that.

Q So that as a practical matter, it's important in the course of discussing treatment of prolapse with a patient that the surgeon and patient together discuss all of the options for her particular condition as well as determining whether or not or what type of surgery that particular surgeon can or should perform?

MR. SLATER: Objection to the form. You can answer.

THE WITNESS: Yeah, that's a long question. I agree with the beginning part. I think I lost you at the end.

BY MS. JONES:

Q You would agree with me that if a surgeon

does not feel comfortable with performing a particular surgical procedure, it would be appropriate for that surgeon to refer the patient to someone else for that procedure?

MR. SLATER: Objection; asked and answered.

You can answer again.

THE WITNESS: Correct.

BY MS. JONES:

Q Let me back up and go to a different topic before I forget this. You never used or implanted Prolift®; correct?

A Correct.

Q You never underwent or participated in any of the professional education programs on Prolift®; correct?

A Correct.

Q You never did any cadaver training with respect to the use of mesh products for pelvic floor repair?

A Correct.

Q I take it you never talked with any of the sales representatives about Ethicon's products or Prolift®?

A Correct.

Q Never reviewed prior to being engaged in this litigation any of the marketing materials for Prolift®?

A Just what I would see in the journals, you know, as I'm reading them.

Q Never saw a surgery involving Prolift®?

A I've seen the surgical videos.

Q The surgical videos that you saw in the context of this litigation?

A Yes.

Q Prior to being retained as an expert in this litigation, you had never seen a surgical video for the implantation of Prolift®?

A Correct.

Q I think it's self-explanatory, but you've never observed a surgery where Prolift® has been used other than on that video that you saw in the context of litigation?

A Correct.

Q Have you participated, Doctor, in the professional educational programs of any manufacturer of pelvic mesh other than Ethicon?

A I have not participated in the professional education for Prolift®.

Q I understand that. My question was not

very artful. I apologize. Have you participated in any professional education program put on by any manufacturer of mesh used in pelvic floor repair?

A No.

Q I had initially restricted my questions to Prolift®, but let me ask this in a broader sense. Have you seen or observed any surgery using transvaginally implanted mesh for pelvic floor repair?

MR. SLATER: You're talking about prolapse now; right?

MS. JONES: Prolapse. I'm sorry.

THE WITNESS: Prolapse. Okay. The answer is no.

BY MS. JONES:

Q Regardless of the manufacturer?

A Correct.

MR. SLATER: That question was vaginal surgery; right?

MS. JONES: Transvaginal, yeah.

BY MS. JONES:

Q Obviously you were never a Prolift® preceptor; correct?

A Correct.

Q Have you ever visited with or spoken to a

Prolift® preceptor?
A Do you mean ever or specific to Prolift® precepting?
Q Specific to Prolift®.
A No.
Q Do you know Prolift® preceptors?
A I know Vince Lucente.
Q Do you know anyone other than Vince Lucente?
A Probably but I don't -- I can't pull out any other names off the top of my head.
Q Were you ever a Prolift® proctor?
A No.
Q Ever speak to a Prolift® proctor about Prolift®?
A No.
Q Before being engaged as an expert in this litigation, had you ever read the Prolift® information for use?
A Instructions for use? No.
Q Instructions for use. I'm sorry.
A No.
Q Had you ever read the IFU for Gynemesh® PS?
A No.

Q Had you ever read the IFU for any other mesh used for pelvic floor reconstruction?
A I may have when I was performing abdominal sacrocolpopexy, and I can't remember the mesh we used, but it's likely I would have read the instructions for use for that product.
Q You just can't remember?
A (Witness shakes head.)
Q Have you ever read the IFU prior to being engaged in this litigation for any transvaginal mesh kit used in pelvic floor repair?
A Again, are we focusing on prolapse specifically?
Q Yes. I'm sorry.
A No.
Q Am I correct, Doctor, that you have never either been employed by or engaged as a consultant for any either pharmaceutical or device manufacturer?
A I have not been.
Q At no time have you ever been requested by either a manufacturer or a regulatory agency to consult on the contents of instructions for use?
A No.
Q Have you ever been requested to advise on

a surgical technique manual?
A For a manufacturer?
Q Produced for a manufacturer.
A No.
Q Have you prior to being engaged in this litigation ever seen a surgical technique manual published by a manufacturer?
A Specific to prolapse or incontinence?
Q Let's talk about specific to prolapse first.
A No.
Q Have you ever seen a surgical technique manual specific to incontinence?
A Yes.
Q Tell me what surgical technique manual you saw.
A The TVT®.
Q Have you seen any surgical technique manual ever published by any manufacturer other than Ethicon?
A Before this involvement?
Q Before this involvement.
A No.
Q Today as you sit here have you seen any surgical technique manuals produced by AMS, for

example?
A Yes.
Q From Boston Scientific?
A No.
Q By Bard?
A No.
Q Do you know whether or not Bard or Boston Scientific had any surgical technique manuals?
A I do not know.
Q What surgical technique manual produced by AMS did you review?
A The Apogee® and the Perigee®.
Q Do you know when AMS first produced that surgical technique manual?
A Roughly early 2000s, '2, '3. I don't know exactly.
Q You've never used Apogee® in your practice; correct?
A Correct.
Q When you were at Magee, was any AMS product used there?
A I don't believe so.
Q While you were at Magee, do you know whether any Bard product or Boston Scientific product was used there?

A I don't know but I can't say for sure not.
MR. SLATER: One second.
(Short recess.)
BY MS. JONES:
Q Doctor, when you did your training on abdominal sacrocolpopexy, you said that you were trained by Dr. Walters?
A Yes.
Q Was that in surgery, hands-on training?
A Yes.
Q Did you do any work in a cadaver lab, for example, to do that surgery, to learn to do the surgery?
A No.
Q Were there any videos or DVDs available to you to help you learn how to do that surgery?
A No.
Q Did you see any slides or PowerPoint presentations about how to do that?
A No.
Q I guess that's almost 20 years ago. Maybe they didn't have those at that time. Did you attend any lectures on how to do that surgery and under what circumstances?
A I had exposure to abdominal

sacrocolpopexy, the teaching of how to perform it, in my residency and in my fellowship, but in actual hands-on performing surgery under the supervision and guidance of Dr. Walters, that occurred in 1993.
Q When you said you had exposure during your fellow --
A Residency and fellowship.
Q -- your fellowship and residency, was that in the form of lectures?
A Yes; and textbooks.
Q Do you have any recollection of how many cases you watched before you actually performed the surgery?
A No, I don't.
Q Was it more than one?
A Yes.
Q Who credentialized you to allow you to do an abdominal sacrocolpopexy at the Cleveland Clinic?
A I don't recall if there was a specific process for that. It would have been my chairman if that process -- I certainly remember that when I joined the staff as to what procedures I would be performing. And I don't remember how we specifically added on subsequent procedures, but it would be my chairman.

Q And would the same thing be true for sacrospinous ligament fixation, for example?
A Well, that -- yes, that would have been, you know, as part of my initial hiring out of fellowship.
Q But it would have been --
A The chairman. My chairman.
Q The chair of your department or your hospital would have been the one that credentialized you that said that you're allowed to perform these surgeries?
A Well, we filled out the form together. Here are the list of procedures. You've done that? Yes. You're trained and experienced in that? Yes. So to my recollection, we did that together.
Q You and the chairman?
A Yes.
Q But the chairman had to sign off on that, if you will, before you were allowed to conduct those surgeries in that hospital?
A Correct.
Q Was that true of all of the surgeries that you performed?
A Yes.
Q And was that true also at Magee when you

went to Pittsburgh?
A I don't remember that specifically, but I imagine a similar process took place.
Q Generally it is the hospitals or the chairs of those departments there that authorize or give the permission to surgeons to perform certain surgeries; correct?
A Yes.
Q Doctor, have you ever talked with a patient who had mesh used for pelvic floor repair and recommended that they file a lawsuit?
A No.
Q I think you told us about your knowledge of potential mesh complications. Have you ever removed a Prolift®?
A No.
Q Or any portion of the mesh of a Prolift®?
A No.
Q Have you ever treated a woman who had a Prolift®?
A No.
Q And I said treated. Have you ever examined a woman who had a Prolift®?
A No.
Q In the course of your teaching, did you

train residents or fellows on the treatment of mesh complications?
A Specific to abdominal sacrocolpopexy and slings, yes.
Q And in terms of the abdominal sacrocolpopexy, what types of treatment did you recommend or suggest to fellows or residents was appropriate in the case of exposures or erosions?
A Depending on the size of the erosion, beginning with topical treatment, estrogen; if there appeared to be an active vaginitis going on, topical antibiotics; if that wasn't successful, then attempt at mesh resection transvaginally; and if that wasn't successful, then mesh resection abdominally.
Q Do you agree that mesh exposures do not necessarily require any treatment?
MR. SLATER: Objection.
You can answer.
THE WITNESS: I must say, my experience in treating patients with mesh erosion has fortunately been limited. I personally would feel uncomfortable unless the patient was ready for frequent follow-up to just watch and wait.
BY MS. JONES:
Q You said that you would -- I don't think

you said this, but I interpreted this -- suggest topical creams. That would be an estrogen cream?
A Yes.
Q And did you find that the estrogen cream was often sufficient to accomplish the healing?
A Again, my clinical experience in managing mesh complications like erosion is limited. Personally I'm not sure that estrogen has -- is effective or whether it's passage of time. No one's studied the most effective way to manage mesh complications.
Q When you say that your experience managing mesh erosions is limited, do you have any idea how many mesh erosions you have treated?
A I would say a handful at most.
Q Five?
A Probably less than five.
Q Have you ever done any mesh resections?
A Only for a TVT®.
Q Never done a mesh resection for an abdominal sacrocolpopexy?
A No.
Q Is there a reason, when you were talking about doing mesh resections, that you would first attempt a vaginal resection before an abdominal

resection?
A To spare the patient another abdominal operation.
Q An abdominal operation is just a far more serious, complicated operation than the vaginal approach?
A It can be.
Q As a practical matter, Doctor, if you've not done a mesh resection, I assume you've done no mesh removals?
A Except for TVT®.
Q Except for the TVT®?
A Correct.
Q And how many mesh removals have you done with the TVT®?
A That would have been at the Cleveland Clinic. So, again, I can't give you a number, but I would say less than five.
Q When we were addressing the mesh resections, generally you would take the most conservative approach first to the treatment of that erosion?
A I personally don't like the word "conservative" because it means so many things to so many people.

Q Would you choose the least invasive?
A It depends. I think if I saw a patient with a very extensive erosion where I felt there was a risk to her, then I don't know if I would feel comfortable wasting -- not wasting time but spending time on something that wouldn't have a great chance of success.
Q You told us, Doctor, that you were aware of a risk of mesh contraction. Did you ever have a patient that you treated for mesh contraction?
A No.
Q You told us that you were aware of the risk of infection associated with the use of mesh. Did you ever have a patient that you treated for infection associated with mesh?
A No.
Q As you sit here today, do you remember treating any patient who had mesh used in an abdominal sacrocolpopexy for any mesh-related complication?
A No.
Q Other than the TVT® that we talked about, do you remember treating any patient at all for any mesh-related complication?
A No.

Q Have you ever examined mesh removed from a patient that had been used to repair prolapse?
A No.
Q Am I correct that you've never then looked at mesh that's been removed under a microscope or held it in any way?
A I have reviewed the histology slides prepared for this case. I haven't handled it in my hands.
Q Prior to being engaged as an expert witness in this case, had you ever looked at pathology slides on mesh?
A No.
Q Prior to being engaged as an expert witness in this case, had you ever held in your hand to examine any mesh removed from a patient other than the transvaginal tape?
A No.
Q Prior to becoming involved in this litigation, had you ever reviewed any photomicrographs of mesh removed from a patient?
A No.
Q Prior to being involved and engaged as an expert in this case, had you ever seen any surgery or observed any surgery to remove mesh from a

patient?
A No.
Q Prior to being engaged as an expert witness in this case, had you ever performed any examination of the porosity of a mesh?
A Now, Dr. Moalli at the University of Pittsburgh is involved in studying mesh characteristics. I am certainly not -- at that time I was not directly involved in her research. I've been in her lab and she's shown me what she's doing. That would be the extent of my answer.
Q You've never been engaged in any research on the porosity of mesh; am I correct?
A Correct.
Q You've never actually measured the size of the pores of mesh; am I correct?
A Correct.
Q You've never actually done any comparison between the different shapes of the pores of mesh; am I correct?
A Correct.
Q You've never done any studies comparing multifilament with monofilament mesh; am I correct?
A Correct.
Q You certainly don't hold yourself out as a

polymer chemist, do you?
A No, I am not a polymer chemist.
Q And I take it that you're not a biomaterials expert?
MR. SLATER: Objection to the form. You can answer.
THE WITNESS: What do you mean by an expert?
BY MS. JONES:
Q Well, do you have any special training in the development of biomaterials?
A Not in the development of biomaterials. Based on my background and my study in this case, I think I have a broad understanding of the input, say, a medical director at Ethicon would give into discussions and decisions surrounding biomaterials.
Q That's not really what my question is, Doctor. Let me ask this: You said based upon your study in this case. Am I correct then that prior to becoming engaged as an expert witness in this particular litigation, you had not studied the characteristics of those meshes?
A Correct.
Q And that means you had never done any laboratory studies on them?

A Correct.
Q Never done any biomechanical studies on them?
A Correct.
Q Never compared the biomechanical studies done on the different types of meshes?
A Correct.
Q Never done any type of comparison upon the characteristics of the different meshes, such as tensile strength or burst point?
A Correct.
Q And you've never done any animal or toxicology studies involving the use of mesh, have you?
A No.
Q I understand that you are a medical doctor, but beyond the standard medical training, do you have any advanced training in pathology?
A No.
Q How about in radiology?
A No.
Q Psychiatry or psychology?
A "Advanced training" meaning?
Q Well, have you ever held yourself out as a psychiatrist?

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A No.
Q Have you obtained any postgraduate education in the field of psychiatry?
A No.
Q Have you ever been granted privileges on staff at any hospital as a psychiatrist or for psychiatry?
A No.
Q You're certainly not Board-certified in psychiatry?
A Correct.
Q It would also be true that you don't hold yourself out as an infectious disease specialist?
MR. SLATER: Objection.
You can answer.
THE WITNESS: I am experienced in caring for the infectious diseases that occur in gynecologic and urogynecologic practice.
BY MS. JONES:
Q There is a subspeciality that's recognized for infectious diseases, isn't there?
A I don't know.
Q You've certainly not been Boarded as an infectious disease specialist?
A No, I am not.

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Q And don't have any advanced training in the field of neurology?
MR. SLATER: Did you say neurology?
MS. JONES: Neuro, N-E, neurology.
THE WITNESS: Certain tests are performed as part of urodynamic testing, for example, that evaluate the muscles and the nerves. So I certainly have training and experience in that.
BY MS. JONES:
Q I'm sorry. You have training and experience in?
A The muscle and nerve testing that is a part of urodynamic studies.
Q And in the course of your work as a surgeon and doing pelvic floor repairs, did you become aware of the potential complication of injury to the pudendal nerve?
A Yes.
Q And did you treat pudendal neuralgia?
A No, I have not had that in my clinical experience.
Q Have you had patients who had pudendal nerve damage?
A Not in my clinical practice, no.
Q Have you ever reviewed, Doctor, the

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federal regulations that pertain to devices?
A I have reviewed some of them.
Q When did you review those?
A Do you mean a date or relative to this case?
Q Relative to this lawsuit.
A Okay. Yes, relative to this lawsuit.
Q But you had never reviewed the FDA regulations prior to becoming engaged as an expert witness in this lawsuit?
A No.
Q I asked a very bad question. I think we've got a double negative there.
Had you ever reviewed the FDA regulations pertaining to devices prior to becoming engaged as a witness in this case?
A No.
Q Had you ever been involved in a clinical trial designed to evaluate the safety and efficacy of a medical device prior to becoming engaged in this lawsuit?
A Yes.
Q What device was that?
A Well, we hadn't decided. This was in the pelvic floor disorders network. We were interested

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in studying mesh products. And that was at a time when the products were rapidly changing, products being brought on the market, taken off the market, changed, put back on the market. And ultimately in my tenure as the program director of the pelvic floor disorders network, we were not confident that we could choose a product and have relevant study results by the time it takes to complete a clinical trial.
Q When was this being considered?
A I would say between 2006 and 2007.
Q Does the pelvic floor network still exist?
A Yes.
Q Does the program at NIH still exist?
A Yes.
Q Who is the current program director?
A I don't know.
Q When is the last time that you had any contact with that network?
A Well, the network itself, not the individuals I assume is what you're meaning. So the following year, the 2008 year, that would -- you know, throughout that year just smoothing over the transition a little bit.
Q Why did you leave your position as program

director?
A I felt that I had accomplished what I wanted to accomplish. The clinical trials network was functioning well. I was confident that it would continue without my leadership. And my health at that time benefited from me reducing the intensity of my workload and the amount of travel I was required to do.
Q So am I correct, if we go back to where we started, that you were never involved in a clinical trial to evaluate the safety and efficacy of a device?
A Correct.
Q Prior to being retained as an expert witness in this lawsuit, had you ever reviewed the patient brochure for Prolift®?
A No.
Q Had you reviewed the patient brochure for any other product?
A Specific to a medical device for prolapse?
Q Right.
A No.
Q Had you ever reviewed the patient brochure for TVT®?
A I believe so.

Q Did you ever counsel with a patient about the patient brochure for the TVT®?
A I don't understand your question.
Q Did you ever use the patient brochure for the TVT® to counsel a patient?
A No.
Q You understand that patient brochures are available through doctors to counsel patients?
A Do I understand they're available?
Q How do you understand that patients get the patient brochures?
MR. SLATER: Objection to the form.
You can answer.
THE WITNESS: The hard copy, the little pamphlet? I would assume they usually pick that up in the doctor's office.
BY MS. JONES:
Q And they are designed to be used in consultation with a physician, are they not?
MR. SLATER: Objection.
You can answer.
THE WITNESS: I don't believe it says -- I take that back. To my mind, they're a marketing device.

BY MS. JONES:
Q Well, let me ask it this way: Would you ever perform a surgery on a patient who came to you and said, Doctor, I've looked at the patient brochure and I want to have a surgery involving this device without first counseling with them?
A No.
Q Did you use patient brochures with the TVT®?
A I did not supply patients with the patient brochure.
Q And that's because you considered them to be a marketing device?
A No. That's because if they were available, it would be someone else's job to make them available to the patient, like the --
Q I don't understand.
A Like the nurse manager of the clinical area deciding what materials would be put out for patients' use.
Q That's something that was put out in your facility and given to patients without the approval of physicians?
A I don't know specifically. I wasn't involved.

Q When you said that you considered the patient brochures to be marketing devices, did you ever use or make available a patient brochure to a patient for any reason?
A For a commercial product?
Q Uh-huh.
A I did not personally do that, no.
Q Do you know whether in any institution with which you were associated the patient brochures for devices were distributed to patients?
A I don't know.
Q Did you ever have a conversation with a patient about the contents of the patient brochure?
A Not that I recall.
Q Do you remember whether or not there were patient brochures with Gynemesh® PS?
A Do I know if they existed?
Q Uh-huh, or whether you used them.
A Prior to being involved --
Q Prior to being involved as an expert witness here.
A I do not know.
Q Am I correct that prior to being involved as an expert witness in this litigation, you have no recollection of ever reviewing a patient brochure on

any mesh product?
A With the patient you mean or just reviewing it for general reading?
Q Just reviewing it. Do you remember ever reading a patient brochure prior to being engaged in this litigation?
A No, I don't recall.
Q Do you ever remember walking into or looking at the brochures at Magee, for example, to see what patient brochures were out there for the patients to look at?
A No.
Q Have you ever used any materials put out by a manufacturer to assist you in counseling a patient?
A I don't recall. Using products was not a big part of my practice.
Q Well, let me ask you a little bit differently. Sometimes there are brochures or publications that may not deal specifically with the product but that may deal with the condition, pelvic organ prolapse, for example. Do you ever remember using any of those types of materials to counsel the patients?
A We had brochures that discussed conditions

that were prepared by the American College of Obstetricians and Gynecologists, and I would use those brochures in speaking with patients.
Q Other than the brochures put out by ACOG, did you use any other materials in counseling the patients?
A Yes. We had prepared materials of our own.
Q And did you, in fact, prepare materials of your own with respect to prolapse?
A I think that was a joint effort with my colleagues in the division.
Q Where, at Magee or at Cleveland Clinic?
A In Cleveland.
Q Can you tell me what the form of that was? Was it just a typewritten description of prolapse or did it cover the types of treatment and the complications or was it more of a brochure?
A I can't recall all the details. What I recall is things like postoperative instructions, how to reach your doctor, things like that.
Q You don't remember then something that was like a description of what prolapse is, what the --
A Well, those are --
Q -- different treatments are?

A Those are the brochures that we used from the American College.
Q You didn't develop a separate brochure on those conditions, for example, and those treatments and the complications that might be associated with it?
A No.
Q At any time, Doctor, while you were practicing before you left the NIH, did you ever take any sabbaticals?
A I think when I first left the NIH, my leave was described as a sabbatical with the possibility I would return. And then I didn't return. Does that answer your question?
Q Well, maybe. What did you do in that sabbatical or did you do anything in that sabbatical?
A It was -- I didn't pursue another degree. It was a general term for not work -- you know, not being in that position any longer with the possibility that I was returning.
THE WITNESS: It is 5 o'clock.
MR. SLATER: I think just go a couple more minutes to finish this line of questioning and that's okay. That's customary.

THE WITNESS: Okay.
BY MS. JONES:
Q I asked you about what surgeries you were permitted to perform or credentialed to perform. How did you go about determining which surgeries you would seek credentialing in?
A It depended on what surgeries I had been experienced in during my training.
Q Fair to say that you only sought credentialing with respect to the procedures that you felt comfortable with?
A Yes.
Q Do you know how many abdominal sacrocolpopexy cases you performed before you felt proficient to do that surgery on your own?
A No, I don't remember.
Q All of the surgeries that you performed involved dissection of tissues, did they not?
A Is that a general question, every surgery --
Q It's just a general question.
A Related to prolapse or every surgery at all?
Q Related to prolapse.
A Yes.

Q Did you use hydrodissection in your practice?

MR. SLATER: Let me just stop here. It's 5 o'clock. It's after 5:00. We had planned to stop at 5:00. I wanted to let you go if you were finishing a line of questioning, but it seems that we're getting into something new now in terms of surgical techniques so I think it's a good stopping point. I'm not going to tell her not to answer this question but --

MS. JONES: That's fine.

BY MS. JONES:

Q If you'll answer this question and if there's a follow-up or two, that would be fine, but then we'll stop.

A We didn't call it hydrodissection. We called it infiltration. We were not entering the vesicovaginal and the rectovaginal spaces with the infiltrate.

Q How did the infiltration differ from hydrodissection?

A Hydrodissection, to my understanding, is a technique in which fluid is injected into the vesicovaginal and/or rectovaginal spaces. This is unique to Prolift®. This is not the way standard

anterior and posterior colporrhaphy, for example, are performed. Does that answer your question?

Q Well, I don't think so. I was asking you about the difference between hydrodissection and the infiltration that --

A Okay. So hydrodissection, again, is in the vesicovaginal space. I'll just talk about that just for simplicity. It's the same for the rectovaginal space, just the opposite, anterior to posterior. You understand.

Infiltration when performing an anterior colporrhaphy is the injection of the infiltrate into the layers of the vaginal wall.

Q Have you ever performed what you describe as hydrodissection?

A No.

MS. JONES: That's it.

MR. SLATER: See you tomorrow at 9:30.

MS. JONES: See you in the morning.

(Witness excused.)

(Whereupon the deposition recessed at 5:08 p.m.)

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CERTIFICATE

I, KIMBERLY A. OVERWISE, a Certified Court Reporter and Notary Public of the State of New Jersey, do hereby certify that prior to the commencement of the examination, ANNE M. WEBER, M.D., M.S., was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

KIMBERLY A. OVERWISE
CCR: 30X100224600
Dated: November 19, 2012

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

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ACKNOWLEDGMENT OF DEPONENT

I, ANNE M. WEBER, M.D., M.S., do hereby certify that I have read the foregoing pages, 1-210, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

ANNE M. WEBER, M.D., M.S. DATE

Subscribed and sworn to before me this ____ day of _____, 2012.

My commission expires:_____

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Notary Public

LAWYER'S NOTES

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